

Registration Form

Offering # **0907-201**

Preparation, Packaging and Labeling of Clinical Trial Materials

8–10 July 2009 • Amsterdam, The Netherlands

Priority Code: **520**

(Please use this code when registering)

Dr./Mr./Ms. _____
Surname Given Name

Job Title _____

Company/Organization _____

Department/Mail Code _____

Mailing Address _____

Postal Code _____ City _____ Country _____

Tel _____ Fax _____

E-mail Address _____

(Required in order to send confirmation material. CfPA does not rent or sell e-mail addresses)

Note: Please complete separate form for each registrant.

Tuition and Payment Methods

Early Registration (Save \$200)
(Must register and pay by 13 May 2009)

U.S. \$ **2375** / \$ **2265**

Single Rate

Group Rate*

Regular Registration

U.S. \$ **2575** / \$ **2465**

Single Rate

Group Rate*

Tuition payable in US funds net of all charges includes luncheon, breaks, text and course notes.

***Group Rate** is per person, for two or more enrollments registering at the same time, from the same company, for the same course.

Note: Payment is due before course start date.

Send Invoice

Purchase Order # _____
(If Required)

Check (payable in U.S. funds to The Center for Professional Advancement)

Bank Transfer (Pay by Bank Transfer to Account No. 62.62.46.628 (US\$) at ABN-AMRO Bank N.V., Postbus 2078, 1000 CB Amsterdam, The Netherlands. The course Offering # (above) and participant's name must be included on bank transfer.)

Credit Card

Visa MasterCard American Express Discover

Card # _____ Exp. Date _____

Cardholder Name _____

Signature _____

ID 858

C8-285

3 Ways To Register

- Internet: www.cfpa.com
- Fax registration form to: +31.20.620.21.36
- Mail registration form to:

The Center for Professional Advancement (CfPA)
Oudezijds Voorburgwal 316A
1012 GM Amsterdam, The Netherlands

General Information

Payment: Tuition payable in US funds net of all charges. Payment is due BEFORE course start date. If payment has not been received two weeks before the course, a credit card will be required to guarantee registration.

Discounts/Rates: To receive the Early Registration Discount, payment is required at time of registration and/or BEFORE early registration discount expires or the regular tuition rate will apply. If choosing invoice/check/wire transfer, payment must be received prior to expiration of early registration discount or the regular tuition rate will apply. All tuition prices are a per person rate. To qualify for the Group Rate tuition, registration must be for two or more enrollments registering at the same time, from the same company, for the same course. Multiple discounts not applicable.

Cancellations/Substitutions/FEES: All cancellations are subject to a \$150.00 processing fee. Applicants may cancel up to two weeks prior to the course start date for a refund. If less than two weeks, a credit will be issued that can be used towards a future course up to one year from the date of issuance. No refunds or credit will be issued for those who do not attend the scheduled course and/or cancel less than two working days before the start date. Substitutions are permitted at any time. If for any reason, CfPA decides to cancel this course, we are not responsible for airfare, hotel or other costs incurred by the registrant. Program content, schedule and instructors are subject to change without notice.

Confirmation Letters: Before each course begins, all registrants will receive written confirmation including detailed information regarding course location – VIA EMAIL. If confirmation is not received two weeks prior to the course please contact Customer Service.

For those requiring visas, confirmation letters will not be sent until payment is received.

Please note: **English** will be used in all lectures and course notes.

Our full terms and conditions can be found on our website at www.cfpa.com

Courses of Interest

- **Auditing and Inspecting Preclinical Research for GLP Compliance**
course id# 1774
- **CMC Submissions in CTD Format**
course id# 1989
- **Early Stage Clinical Studies for Drugs and Devices**
course id# 2118
- **Good Clinical Practices (GCP)**
course id# 107
- **INDs, NDAs vs CTDs Global Regulations**
course id# 448
- **Process Validation for Packaging of Pharmaceuticals and Medical Devices**
course id# 1789

Who We Are

The **Center for Professional Advancement (CfPA)** is the largest accredited technical training organization in the world with a curriculum of approximately 350 short courses in 18 industries including Pharmaceutical, Biotechnology, Medical Device, Chemical, Cosmetics, Food and more.

Since our founding in 1967, we have successfully trained nearly a half million people worldwide in topics ranging from basic and introductory concepts to new advances and cutting-edge technology, and current U.S. and European regulations. CfPA courses are offered in a variety of formats – Public offering, Client Site and Online – to fit you or your company's training needs.

Accreditations



The **Center for Professional Advancement** has been approved as an Authorized Provider by the **International Association for Continuing Education and Training (IACET)**, 8405 Greensboro Drive, Suite 800,

McLean, VA 22102. In obtaining this approval, **The Center for Professional Advancement** has demonstrated that it complies with the ANSI/IACET Standards which are widely recognized as standards of good practice internationally. As a result of their Authorized Provider membership status, **The Center for Professional Advancement** is authorized to offer IACET CEUs for its programs that qualify under the ANSI/IACET Standards.



The **Center for Professional Advancement (CfPA)** is accredited by the **Accreditation Council for Pharmacy Education** as a provider of continuing pharmacy education. **Continuing Education Units (CEU)** will be awarded only upon successful completion of the course, i.e., attendance at essentially all the formal sessions and submission of a course evaluation. The **CEU** rate is 0.1 **CEU** per contact hour; statement of credit will be mailed within six weeks. You will have an opportunity to evaluate your successful completion of these course objectives through a **Learning Assessment**. *This offering is Program# 716-000-08-126-L04*

SAVE \$200-Register & Pay by 13 May

8–10 July 2009
Amsterdam, The Netherlands

Preparation, Packaging and Labeling of Clinical Trial Materials

Course Topics Include:

- Production/Validation/Compliance
- Packaging/Blinding/Distribution
- IVR
- Contract Manufacturing and Packaging
- The Quality Unit
- International Perspective of the Industry
- Case Studies

Directed by:

Dr. Efreem Zaret
President
EZ Associates, Inc.

The Center for Professional Advancement

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www.cfpa.com



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Who Should Attend

This survey course will emphasize the procedures and techniques needed to prepare compliant clinical trial supplies. The course is intended for personnel who are new to the clinical supply process as well as for those who have experience in Clinical Trial Materials (CTM) preparation but want to update or refresh their knowledge. This includes, but is not limited to, those involved in:

- Packaging
- Quality Assurance/Control
- Regulatory Affairs
- Contract Packaging
- Labeling
- Clinical Manufacturing
- Research & Development

Learning Objectives

Upon completion of this course, you will be able to:

- Define the scope of activities necessary to provide quality materials for clinical studies
- Demonstrate knowledge of clinical trial materials that are intended for use in the United States in addition to compliance requirements and techniques needed for supplies to be used in Europe and other parts of the world
- Identify the rationale of the clinical process and provide the fundamentals of regulatory compliance and labeling of clinical supplies

Course Description

The aim of this survey course is to provide an **overview and introduction** to the many details that must be considered in the design, preparation, packaging, labeling and distribution of clinical trial materials in support of adequate and well-controlled clinical studies. Emphasis will be given to practical examples of procedures, components, and regulatory requirements needed to provide acceptable investigational materials. Comparison of the requirements of the United States and Europe and consideration of the harmonization of international clinical studies will be given.

The interrelationships of the industrial pharmacist, clinical research associate, medical monitor, regulatory officer, clinical pharmacist, clinical supplies and quality assurance/control personnel will be discussed. In addition, cGMP will be reviewed to ensure compliance during the preparation, use and return of the trial materials.

The course provides participants the opportunity to share experiences with faculty and colleagues about effective methods to design, produce, package, and label clinical trial materials. The concepts presented during the course are integrated by means of case studies that consider real-world clinical trial supply problems and solutions.

Preparation, Packaging and Labeling of Clinical Trial Materials

COURSE OUTLINE

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First Day

08:00: Registration

08:30–17:00:

Morning:

- Introduction and Welcome
- The Drug Development Process
- The Clinical Supply Organization
- Current cGMPs
 - Good Clinical Practices
 - EU Guidelines for Investigational Medicinal Products
 - EU GMP's
 - 21 CFR Parts 210 and 211
- Regulatory Websites
- History of US Drug Regulation and the Role of the FDA
- Dosage Forms and Formulations
- Clinical Trial Protocols and Design

Afternoon:

- Introduction to Packaging and Labeling
- Packaging and Labeling for a Clinical Trial
- Case Study 1

Second Day

08:30–17:00:

Morning:

- Labeling of Clinical Trial Materials
- Case Studies 2A and 2B

Afternoon:

- Shipment and Distribution of Clinical Trial Materials:
- Distribution Control Techniques
- Cold Chain Distribution
- Case Study 3

Text

The text for this course **included in the fee** *Introductory Clinical Trial Materials Training Guide* (Tampa, FL: International Society of Pharmaceutical Engineers). www.ISPE.org

Third Day

08:30–15:00:

Morning:

- Case Study 4
- Comparator Drugs for Clinical Trials
- Contract Clinical Manufacturing/Packaging
- Clinical Supplies Returns, Accountability, Reconciliation and Destruction

Afternoon:

- Stability
- Validation
- Packaging Materials and Techniques
- Discussion/Q&A

www.cfpa.com

Client Site

Training at your site and at your convenience. For further information, please contact **Client Site** Programs: Direct Dial (USA) +1/732.238.1600, ext. 4549; or fax +1/732.238.9113; or **E-mail** clientsite@cfpa.com.

Online Training Now Available

A NEW way to experience our accredited training, easily access the knowledge you need through the Internet. For a list of upcoming courses visit www.cfpa.com/online-training.

Course Director

Dr. Efreim Zaret, President of EZ Associates, Inc., is actively engaged in consulting assignments involved with quality assurance/control, preparation and logistics of clinical supplies, regulatory compliance and documentation, and laboratory evaluation of the physical and chemical properties of clinical trial materials and investigational drugs. He has twenty-five years of industrial experience in the development, manufacturing, packaging and evaluation of drugs, foods and other regulated products at the Hartz Mountain Corporation, American Home Products Corporation and for industrial clients in the United States and in Europe. Dr. Zaret obtained his B.S. in Chemistry from the Illinois Institute of Technology and his M.S. and Ph.D. degrees in Organic Chemistry from the University of Wisconsin-Milwaukee.

Additional Faculty

Thomas Miller is a Senior Project Manager at Aptuit, Inc., which provides contract packaging, labeling and distribution services for the biotech and pharmaceutical industries. Mr. Miller has been the clinical supplies project lead in studies covering all phases of clinical studies, including many different indications, and encompassing most regions of the globe. Within each project, he is responsible for the packaging and labeling design and production (including child resistance), as well as the ultimate distribution and final reconciliation.

Mr. Miller received his Bachelor's degree in Biology at Rutgers, the State University of New Jersey. Prior to joining Aptuit, he spent 10 years in the biotech industry as a Researcher and Laboratory Manager.

Course Location

This course will be held at the **Amsterdam American Hotel**. The hotel is holding a limited block of rooms at a reduced rate for course participants. To obtain the preferred rate, you must inform the hotel that you are registering for this course. To ensure accommodations, reservations must be made at least four weeks prior to the course.

Amsterdam American Hotel

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1017 PN Amsterdam, The Netherlands
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