

Registration Form

Offering # **0806-105**

Active Pharmaceutical Ingredients

2-4 June 2008 • 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 _____

How did you learn about this course?

- Direct Mail Colleague Website Other

Tuition and Payment Methods

Early Registration (Save \$200) U.S. \$ **2345** / \$ **2235***
(Must register and pay by 7 April 2008) (Group Rate)

Regular Registration U.S. \$ **2545** / \$ **2435***
(Group Rate)

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

Payment is due prior to course start date. If payment has not been received two weeks before the course, a credit card will be required to guarantee admittance.

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

Send Invoice (POs must be received in advance of course)

Purchase Order # _____

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 at ABN-AMRO Bank N.V., Postbus 407, 1000 AK Amsterdam, The Netherlands. The course no. (above) and participant's name must be included on bank transfer.)

Credit Card Visa MasterCard American Express

Card # _____ Exp. Date _____

Cardholder Name _____

Signature _____

ID 840

C7-278

3 Ways To Register

- Log on to www.cfpa.com
- Fax to: +31.20.620.21.36
- Mail: **The Center for Professional Advancement (CfPA)**
Oudezijds Voorburgwal 316A
1012 GM Amsterdam, The Netherlands

General Information

Discounts/Rates: Early registration discount requires payment at time of registration and before expiration or regular tuition will apply. Group Rate is for two or more enrollments registering at the same time, from the same company, for the same course. Multiple discounts not applicable.

Cancellations/Substitutions: 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. If confirmation is not received two weeks prior to the course please contact us.

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.

For our full terms and conditions, visit www.cfpa.com.

Accreditations



The Center for Professional Advancement has been reviewed and approved as an Authorized Provider (#640) of continuing education and training programs by the **International Association for Continuing Education and Training (IACET)**. **Continuing Education Units (CEU)** will be awarded for participation in this course at a rate of 0.1 CEU per contact hour. *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 Center for Professional Advancement (CfPA) is accredited by the **Accreditation Council for Pharmacy Education** as a provider of continuing 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# 716-000-08-127-L04*

Who We Are

The **Center for Professional Advancement (CfPA)** is the largest accredited technical training organization in the world with a curriculum of approximately three hundred and fifty 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.

Courses of Interest

- **Drug Product Stability and Shelf-Life**
course id# 599
- **Drug Specifications for API's and Drug Products**
course id# 1918
- **Excipient GMPs**
course id# 2050
- **Granulation, Tableting and Capsule Technology**
course id# 541
- **ICH-Q7**
course id# 2091
- **Microencapsulation and Particle Coating**
course id# 774
- **Powder Mixing Technology**
course id# 777
- **Powders: Their Properties and Processing**
course id# 117
- **Tablet Production for Operators and Supervisors**
course id# 1428

The Center for Professional Advancement

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www.cfpa.com

Register by 7 April and **SAVE \$200**

2-4 June 2008
Amsterdam, The Netherlands

Active Pharmaceutical Ingredients

Meeting Today's Production, Control,
and Regulatory Challenges

Course Topics Include:

- Government Regulations
- Buildings & Facilities
- Equipment Utilization
- Process Validation
- FDA Inspections

Directed by:

Richard G. Einig, Ph.D., RAC, CQA
Pharmaceutical Quality Assurance Consultant



CfPA

The Center for Professional Advancement
Accredited Technical Training Worldwide

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Who Should Attend

This course is for individuals working in all phases of human and veterinary Active Pharmaceutical Ingredients (API) production and control including:

- Pilot and commercial production
- Regulatory affairs
- Engineering
- QA/QC
- Process development
- Management

The course models a GMP compliant API operation, everyone's role in achieving compliance, and penalties for noncompliance. Government investigators who inspect API operations are encouraged to attend.

Learning Objectives

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

- Define requirements for the design and operation of an API facility
- Compare your current operation against the latest industry techniques
- Prepare and execute validation procedures
- Design and operate efficient and compliant documentation systems
- Build a quality culture that contributes to overall operational performance

Course Description

This course prepares attendees to meet the challenges they face in this heavily regulated industry. It is vital for API producers to ensure that GMP principles are applied to API production and control, and to demonstrate knowledge of FDA, ICH and other governmental and industry guidance documents.

This course will provide guidance in the design, construction, and validation of GMP pilot and production facilities. Examples of facilities will be discussed. The selection, qualification, and cleaning of equipment will be included with specific examples. Process validation is of singular importance and validation principles and their application will be demonstrated with examples. Process development and technical transfer reports will be described. The function of the quality unit to establish and manage the systems required to maintain compliance will be discussed. Throughout the program there will be interactive class exercises. On the last day of the course participants will receive instruction on managing an FDA inspection followed by a workshop in which participants prepare written responses to simulated FDA-483s (List of Inspectional Observations) based on actual FDA observations. The exercise will result in a valuable exchange of information and approaches with your colleagues.

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COURSE OUTLINE

first day

08:00: Registration

08:30: Introduction

08:45-10:00:

FDA Regulation of API Production:

- The Essentials for Understanding Current Good Manufacturing Practice Requirements
- FDA Guides, Guidelines, and "Guidances"
- Other Sources of Regulatory Guidance
- Industry and Regulatory Policy
- A Word on Course Exercises

10:15-12:00:

Building and Facility for API Production:

- Facility Design Considerations
- Process Equipment Selection
- Equipment Qualification
- Equipment Cleaning Systems

13:00-13:45:

Interactive Exercise

13:45-14:30:

Equipment Utilization in API Operations

- Process Analytical Technology

15:00-15:30:

- Highly Bioactive Containment Facilities
- Ancillary Support Systems

15:30-17:00:

Processing in API Operations

- Process Water Quality
- Automation

second day

08:30-10:00:

Technical Transfer/Initiating Operations:

- General Organizational Considerations
- Milestones of the Technical Transfer Process
- Documentation – R&D to Commercialization
- Key Quality Systems Necessary for Success
- Recovery, Reprocessing and Rework

10:30-12:00:

Validations:

- General Validation Considerations
- Processes
- Analytical Methods
- Computer Systems

13:00-14:00:

APIs for Clinical Material:

- General Considerations
- Comparison with Commercial Production

14:00-14:30:

Interactive Exercise

15:00-16:00:

Quality Unit:

- Structure and Responsibilities
- Quality Assurance/Quality Control
- Quality Systems

16:00-17:00:

Auditing API Facilities:

- Type, Purpose, and Preparations
- Performance and Follow-up
- Vendor-Customer Relationship

third day

08:30-10:00:

Preparing for and Managing FDA Inspections:

- The Authority, Approach, and Variability of Investigators
- Pre-inspection Audits
- Pre-inspection Planning
- Responding to FDA Observations During and After the Inspection
- The FDA-483 in Perspective
- Regulatory Actions Available to FDA

10:30-12:00:

FDA Inspection Workshop—Controlling the Damage:

- Simulated FDA-483s, based on actual FDA-483 citations, will be given to small groups for evaluation and the preparation of written responses designed to convince FDA that regulatory action will not be necessary.

13:00-14:30:

Group Presentation of Written Responses:

This workshop has proven an excellent means to share individual experiences and views and to bring into focus the operational and regulatory issues covered in the course. The responses will be presented to all course participants for discussion and constructive critique.

14:30-15:00:

Wrap-Up with Question and Answers

Text

The text for this course **included in the fee** is **Mini-Handbook Q7A - US** Item # GMP045US

Course Director

Richard G. Einig, Ph.D., RAC, CQA is a consultant specializing in the pharmaceutical and veterinary medicine industries. His experience spans over twenty years in senior management of quality, regulatory, and development units of large international companies and start-up "biotechs". He has worked internationally with innovator and generic dosage form companies, medical device manufacturers and research organizations.

Dr. Einig participated in developing the PhRMA Bulk Pharmaceutical Committee's Guidance on Production of Drug Substance, and is an invited speaker at domestic and international meetings on quality and processing of pharmaceutical products.

Dr. Einig is a member of the American Chemical Society as well as a member and carries certifications from the American Society for Quality, the Regulatory Affairs Professional Society, and the Institute for Independent Business. He received undergraduate and graduate degrees in Chemistry from St. Louis University, MBA from Webster University, and PhD from Missouri University.

Additional Faculty

Dale E. Cooper worked for the FDA for thirty-two years. He retired as an Assistant Regional Director. He worked in FDA's foreign inspection program for over 20 years as an investigator. He has written several articles related to the regulation of API producers and the history of the pharmaceutical industry. He is now a consultant.

Michael Day has a thirty year career associated with process development and manufacturing in the pharmaceutical business. He was responsible for U.S. API production for Hoechst-Celanese Corporation and manager of Technical Services for Searle/Pharmacia/Pfizer at the Augusta, Georgia facility. He has extensive experience in the area of technical transfers and associated quality systems that supported commercialization of those products. He is currently consulting and teaching in the pharmaceutical arena.

Course Location

This course will be held at the **NH Amsterdam Centre 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.

NH Amsterdam Centre Hotel
Stadhouderskade 7
1054 ES Amsterdam, The Netherlands
Phone: +31/20/685.13.51
Fax: +31/20/685.16.11

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.

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