

Registration Form

Course Offering # **1003-402**

Active Pharmaceutical Ingredients

March 22–24, 2010 • New Brunswick, NJ

Priority Code: **520**
(Please use this code when registering)

Dr. Mr. Ms. _____
First Name Last Name

Job Title _____

Company/Institution _____

Company Address _____

City _____ State _____ Zip _____

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 January 25, 2010)

U.S. \$ Single Rate **1750** / \$ Group Rate* **1670**

Regular Registration

U.S. \$ Single Rate **1950** / \$ Group Rate* **1870**

Tuition payable in US funds net of all charges includes continental breakfast, 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/Bill Me Purchase Order # (if Required) _____

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

Credit Card Visa MasterCard American Express Discover

Card # _____ Exp. Date _____

Cardholder Name _____
(As appears on card)

Signature _____ Security code _____
(3 or 4 digit code)

Credit card billing address (if different than above address)

3 Ways To Register

- Internet: www.cfpa.com
- Fax registration form to: **732.238.9113**
- Mail registration form to:

The Center for Professional Advancement (CfPA)
P.O. Box 7077
East Brunswick, NJ 08816-7077

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, refunds and credits are subject to a \$150.00 processing fee. Applicants may cancel up to four (4) weeks prior to the course start date for a refund. Applicants that cancel less than four (4) weeks prior to the course will be issued a credit 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 cancel less than ten (10) working days before the course start date and/or do not attend the scheduled course. 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 questions/more information contact Customer Service at 732-613-4500 or info@cfpa.com

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

Courses of Interest

- **Drug Product Stability and Shelf-Life**
course id# 599
- **Excipient GMPs**
course id# 2050
- **Granulation, Tableting and Capsule Technology**
course id# 541
- **ICH-Q7**
course id# 2091
- **Powders: Their Properties and Processing**
course id# 117
- **Tablet Production for Operators and Supervisors**
course id# 1428

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# 716-000-09-127-L04*



ASQ Certification: ASQ Certified Quality Engineers, Reliability Engineers and Quality Auditors may earn recertification credits for attending this program, providing it is covered under one area of the body of knowledge in which they are seeking recertification or is job enhancement.

The Center for Professional Advancement

P.O. Box 7077, East Brunswick, NJ 08816-7077

Phone: 732.238.1600 • Fax: 732.238.9113

E-mail: info@cfpa.com

www.cfpa.com

SAVE \$200-Register & Pay by Jan 25

March 22–24, 2010
New Brunswick, NJ

Active Pharmaceutical Ingredients

Meeting Today's Production, Control, and Regulatory Challenges

Course Topics Include:

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

Directed by:

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



CfPA

The Center for Professional Advancement
Accredited Technical Training Worldwide

www.cfpa.com

Who Should Attend

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

- Pilot and commercial production
- Technical services
- Process development
- Regulatory agency investigators
- QA/QC
- Regulatory affairs
- Validation

The presenters discuss requirements for a GMP compliant API operation, everyone's role in achieving compliance and penalties for noncompliance.

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 to recent industry practices and initiatives
- Identify and better understand FDA regulatory requirements and enforcement activities
- 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 the heavily regulated pharmaceutical industry. API manufacturers must ensure that GMP principles are applied to API production and there is extensive focus on relevant operational, control, and regulatory activities with specific examples. This information is essential for successfully meeting GMP requirements that are sometimes only incompletely expressed by official regulatory guidance documents including ICH Q7.

Some of the topics discussed are design, construction and qualification of GMP production facilities; selection, qualification and cleaning of equipment; process development and technical transfer; validation principles and process validation. Regulatory agency compliance oversight, and duties of the quality unit to establish and manage systems required to maintain compliance will be discussed. Throughout the program there are interactive class exercises. On the last day of the course, participants receive instructions 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.

Active Pharmaceutical Ingredients

COURSE OUTLINE

March 22–24, 2010 • New Brunswick, NJ | Offering# 1003-402

First Day

8:00 a.m.: Registration/Continental Breakfast

8:30 a.m.: Introduction

8:45–10:00 a.m.: FDA Regulation of API Production:

- The Essentials for Understanding Current Good Manufacturing Practice Requirements
- FDA Guides, Guidelines, and Guidances including ICH-Q7
- Other Sources of Regulatory Guidance
- Industry and Regulatory Policy

10:30–12:00 noon: Building and Facility for API Production:

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

1:00–1:45 p.m.: Interactive Exercise

1:45–2:30 p.m.: Roles and Responsibilities for API Production

3:00–3:30 p.m.

- Statistics for Risk-based Operation
- Process Analytical Technology

3:30–5:00 p.m.: Processing in API Operations:

- Process Water Quality
- Automation

Second Day

8:30–10:00 a.m.: Technical Transfer/Initiating Operations:

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

10:30–12:00 noon:

Validations:

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

1:00–2:00 p.m.: APIs for Clinical Material:

- General Considerations
- Comparison with Commercial Production

2:00–2:30 p.m.: Interactive Exercise

3:00–4:00 p.m.: Quality Unit:

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

4:00–5:00 p.m.: Auditing API Facilities:

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

Third Day

8:30–10:00 a.m.: 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 noon: 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 is not necessary.

1:00–2:30 p.m.: Group Presentation of Written Responses:

This workshop has proven to be 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.

2:30–3:00 p.m.: Wrap-Up with Question and Answers

Text

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

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. 4547; or fax +1/732.238.9113; or **E-mail** clientsite@cfpa.com.

Online Training Now Available

A convenient and cost-effective 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

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 Ph.D. from Missouri University.

Additional Faculty

Dale E. Cooper served with the FDA for thirty-two years and retired as an Assistant Regional Director. As investigator he was responsible for many legal actions including injunctions. He was part of FDA's foreign inspection program for over 20 years. 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 in the **Hyatt Regency** located in **New Brunswick, New Jersey**. A limited block of rooms in the hotel will be held for our registrants until four weeks before the course. Participants must, however, make their own reservations; the cost of hotel accommodation is not included in the course fee. Hotel information will be included with your acceptance. To receive **CFPA's** rate and room block, be sure to mention that you will be attending one of our courses. For reservations call 800.233.1234; outside U.S. call 732.873.1234.