## Registration Form

Course Offering # **1201-401**

**Sterile Products: Formulation, Manufacture and Quality Assurance**

January 24–26, 2012 • Burlingame, CA

**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

| | Single Rate | Group Rate* |
|---|---|---|
| **Early Registration (Save $200)** (Must register and pay by December 13, 2011) | U.S. $1750/ | $1670 |
| **Regular Registration** | U.S. $1950/ | $1870 |

Tuition payable in US funds **net of all charges includes continental breakfast, luncheon, breaks 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)

_____

_____

ID 435 C1-100

## 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 $200.00 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. We recommend that travel/hotel arrangements not be made until final confirmation package is received. 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

- **Critical Process Cleaning and Cleaning Validation**
  course id# 1867
- **Drug Product Stability and Shelf-Life**
  course id# 599
- **Lyophilization Technology**
  course id# 279
- **Microbiological Control and Validation**
  course id# 902
- **Packaging of Pharmaceuticals**
  course id# 42
- **Sterilization in the Pharmaceutical Industry**
  course id# 2075

## 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),** 1760 Old Meadow Road, Suite 500 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. **The Center for Professional Advancement** is therefore authorized to offer IACET CEUs for its programs that qualify under the ANSI/IACET Standards. CEUs will be awarded only upon successful completion of the course, i.e., attendance at essentially all the formal training and a minimum score of 70% on the assessment.

**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 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 program provides a knowledge-based activity, applicable to both Pharmacists and Technicians. *This Program# 716-000-09-166-L04-P and 716-000-09-166-L04-T offers a total of 18 contact hours.*


**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 Dec 13***

January 24–26, 2012
Burlingame, CA

# Sterile Products:
## Formulation, Manufacture and Quality Assurance

**Course Topics Include:**

- Formulation and Manufacture of Solutions, Suspensions and Lyophilized Products
- Stability
- Freeze-Drying Principles
- Sterile Packaging
- Sterile Unit Operations
- Sterilization Principles
- Aseptic Processing
- Particulate Matter
- GMP Trends

Directed by:
**Dr. Michael J. Akers**
Senior Director of Pharmaceutical R&D
Baxter BioPharma Solutions

Celebrating 45 YEARS 1967-2012

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**The Center for Professional Advancement**
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## Who Should Attend

This **overview** course is intended for those having specific responsibilities in the areas of sterile drug product science and technology. It will be of particular value to those in:

- Research
- Development
- Production
- Quality Assurance and Control

Those who wish to broaden their appreciation of these technologies and review the latest developments, as well as managers who have responsibility for a broader base of activities will find the course of interest.

## Learning Objectives

Upon completion of this course, you will have an appreciation of current parenteral systems and some insight into parenteral systems of the future. You will also be able to:

- Define the unique characteristics of sterile dosage forms, how these characteristics are achieved and maintained
- Recognize the significant developments and special procedures important in the use of these products
- Identify the various current and some advanced formulation approaches, parenteral packaging systems, special stability requirements and manufacturing processes and controls used to obtain a quality sterile product
- Describe the aseptic manufacturing processes and all unit operations involved in sterile product manufacturing and control, including sterilization, filtration and lyophilization
- Outline the facility, personnel, and microbial control requirements, fostering an appreciation of the distinctive requirements of sterile products and acquaintance with quality control procedures and international regulations
- List the trends in cGMP compliance as applied to sterile product manufacturing and control

## Course Description

This **comprehensive** course provides an appreciation and general understanding of the overall contemporary state of science and technology associated with the design, development and manufacturing of sterile drug dosage forms. Emphasis will be oriented toward formulation development and product manufacture of quality sterile dosage forms that meet or exceed expected good manufacturing practice requirements.

# Sterile Products: Formulation, Manufacture and Quality Assurance

***COURSE OUTLINE***

January 24–26, 2012 • Burlingame, CA | Offering# 1201-401

## First Day

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

**8:30–10:00 a.m.: Review of Learning Objectives/Overview of the Sterile Dosage Form:** Definitions, types and classification of sterile products, historical review, advantages and disadvantages, basic characteristics and requirements, routes of administration, needles, hazards of parenteral administration.

**10:30–12:00 noon: Formulation of Solutions:** Principles of designing stable sterile solutions, formulation approaches used to overcome problems with drug solubility and stability. Coverage of solvent systems and additives (solubilizers, stabilizers, preservatives, competitive binders, and tonicity adjusters) used in small molecule and biopharmaceutical sterile dosage forms. Some coverage of sterile packaging systems and advances in packaging for convenient delivery of injectable products.

**1:00–2:30 p.m.: Formulation of Dispersed Systems:** Focus primarily on design, development and manufacture of macrosuspensions (including vaccines) with some coverage of micro-and nanosuspensions. Also basic formulation of emulsions and liposomes.

**3:00–4:30 p.m.: Formulation of Lyophilized Products:** Steps in the development of freeze-dried formulations, packaging and processes with focus on proteins. Freezing effects on stability, critical temperature determination, molecular mobility, product collapse. Thorough coverage of additives with focus on stabilizers and their mechanisms. Introduction of the interplay between formulation and cycle development. Also some coverage of new delivery systems for lyophilized products.

## Second Day

**8:30–10:00 a.m.: Preparation for Sterile Manufacturing:** Application of GMP regulations to sterile manufacturing, facility and personnel requirements, air systems, room classification, equipment and packaging preparation, overview of complete process.

**10:30–12:00 noon: Sterile Manufacturing Unit Operations:** Water for injection, compounding and mixing, filtration, filling, stoppering, sealing, and finishing, some discussion of isolator technology, what can go wrong during manufacturing and how to overcome.

**1:00–2:30 p.m.: Processing of Lyophilized Products:** Description of equipment, cooling and drying phases, process optimization. Temperature, pressure, formulation and packaging effects on process and final product quality. Some discussion of scale-up, technology transfer, and process validation.

**3:00–4:30 p.m.: Sterility Assurance:** Basics of microbiology, components of contamination control, cleaning and sanitization, depyrogenation, sterilization, aseptic processing, environmental monitoring. Aseptic process validation with emphasis of FDA guidelines for aseptic processing and coverage of EU GMP guidelines for manufacture of sterile medicinal agents.

## Third Day

**8:30–10:00 a.m.: QC Testing-Sterility, Endotoxin, and Stability:** Basic principles and methods in sterility testing, pyrogen testing, endotoxin testing and GMP stability testing. Review of major degradation mechanisms for injectable drugs, and FDA/EU stability requirements for NDA and ANDA submissions.

**10:30–12:00 noon: Visual Inspection and Particulate Matter:** Methods involved in human and mechanical inspections for visible particles (and other product defects), requirements and systems for subvisible particulate matter evaluation, discussion of current issues with visual inspection practices and acceptance criteria especially for biological products.

**1:00–2:30 p.m.: Quality by Design and GMP Trends:** Discussion of main features of QbD requirements, History of GMP regulations, preapproval FDA inspections, history of product recalls, FDA and MHRA inspectional trends, recent FDA warning letter citations.

**3:00–4:00 p.m.: Open Forum:** Q&A session over any topic covered or topics not covered in the field of parenteral science and technology.

**Assessment Opportunity**

*Formulation and processing case studies and answers will be included in the course notes, but not necessarily covered in lecture.*

*References and certain tables/attachments also in back of course notes.*



**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

**Dr. Michael J. Akers** has taught sterile product courses for 35 years. He has 40 years of experience in the development and manufacture of sterile dosage forms including solutions, suspensions, ophthalmics and freeze dried products. He has contributed to the filing of eleven new drug applications including Humulin® Cartridges and Gemzar®. Currently Dr. Akers is Senior Director of Pharmaceutical Research and Development for Baxter BioPharma Solutions in Bloomington, IN. Previously, he served as an independent consultant for the parenteral industry with over 60 clients. His background includes significant experiences at Searle (now Pfizer), Alcon, and Eli Lilly. He also was professor of pharmaceutics at the University of Tennessee College of Pharmacy and currently is adjunct professor at six schools of pharmacy. He has authored, co-authored, or edited 4 books and 20 book chapters including the chapter on Parenteral Products that will appear in the new 22nd edition of *Remington's The Science and Practice of Pharmacy*, 2012.

## Additional Faculty

**Dr. Gregory A. Sacha** is a research scientist for Baxter BioPharma Solutions in Bloomington, IN. He received a BS in Pharmacy from Butler University in 1993 and a PhD in Industrial and Physical Pharmacy from Purdue University in 1999. His experience includes technology transfer, scale-up and process improvement for solid oral and parenteral manufacturing processes. Dr. Sacha is currently involved in formulation and process development for sterile products and supports process improvement for full-scale manufacturing operations.

## Recommended Reading

The Course Director recommends, as an *optional resource*, the text ***Sterile Drug Products: Formulation, Packaging, Manufacturing, and Quality*** by Michael J. Akers (Informa Healthcare, 2010).

## Course Location

This course will be held in the **San Francisco Bay, CA** area. Specific hotel information will be sent to you in your final confirmation package which will be emailed to you approximately three (3) weeks prior to the course start date. Please note that participants must make their own hotel reservations; the cost of the hotel accommodations is not included in the course fee. We recommend that travel/hotel arrangements not be made until final confirmation package is received.