

Registration Form

Course Offering # **0910-404**

Lyophilization Technology

October 19–21, 2009 • 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 August 24, 2009)

U.S. \$ Single Rate **1740** / \$ Group Rate* **1660**

Regular Registration

U.S. \$ Single Rate **1940** / \$ Group Rate* **1860**

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

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 _____

Signature _____

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 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 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

- **Active Pharmaceutical Ingredients**
course id# 840
- **Drug Product Stability and Shelf-Life**
course id# 599
- **Granulation, Tableting and Capsule Technology**
course id# 541
- **ICH-Q7A**
course id# 2091
- **Pharmaceutical Process Development**
course id# 1358
- **Sterile Products: Formulation, Manufacture and Quality Assurance**
course id# 435

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# 716-000-09-163-L04*

SAVE \$200-Register & Pay by Aug 24

October 19–21, 2009

New Brunswick, NJ

Lyophilization Technology

The Theory and Practice of Freeze Drying

Course Topics Include:

- Theory of Freeze Drying Aqueous Solutions
- Freeze Drying Cycles
- Rational Formulation for Lyophilization
- Specification, Manufacture and Qualification of a New Freeze Dryer
- Cycle Development
- Quality Control and Validation
- Open Discussion with Case Studies

Directed by:

Dr. J. Jeff Schwegman

Founder and CEO of AB BioTechnologies



CfPA

The Center for Professional Advancement
Accredited Technical Training Worldwide

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

Who Should Attend

This course is designed for personnel in the pharmaceutical, diagnostic, biomedical engineering and biotechnology industries responsible for the specification, development and production of lyophilized products, including:

- Biochemists
- Chemists
- Chemical Engineers
- Microbiologists
- Pharmacists
- R & D Personnel
- Pilot Plant Operations
- Production Supervisors
- Managers
- QA/QC

Those new to the industry and those with previous experience will find the course beneficial.

Learning Objectives

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

- Identify the physical, physico-chemical and engineering principles of freeze-drying, the nature and persistence of glassy states, the collapse phenomenon, secondary drying and residual moisture, introductory concepts of heat and mass transfer and their influence on freeze-drying
- Formulate for freeze-drying and establish the most efficient freeze-drying cycles
- Define the factors involved in process scale-up, control and optimization
- Outline regulatory requirements and the validation of the lyophilization product and process

Course Description

This course is designed to provide participants with an **up-to-date understanding** of the theory and practice of lyophilization. Freeze-drying (lyophilization) will be presented and explained in physical, physicochemical, biochemical and engineering terms. Theory and practice will be interrelated and biotechnological and pharmaceutical applications will be emphasized. Participants should acquire a comprehension that transcends common disciplinary boundaries.

Topics covered will include vacuum physics, properties of water and ice, supercooling and supersaturation, phase behavior during freezing, differential thermal analysis, electrical resistance, glassy state behavior, collapse phenomena, desorption phenomena, product formulation, heat and mass transfer, development of freeze-drying cycles, end point determination, residual moisture, product stability, process scale-up, process control and optimization, Current Good Manufacturing Practice (cGMP), and validation. Fault finding and problem solving will be presented using case studies.

Lyophilization Technology

COURSE OUTLINE

October 19–21, 2009 • New Brunswick, NJ | Offering# 0910-404

First Day

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

8:30–9:00 a.m.: Director's Opening Address
• Course introduction and format

9:00–10:00 a.m.: Introduction to Freeze-Drying

- Basic theory and brief history
- Temperature/pressure monitoring devices

10:30–11:00 a.m.: Physical Properties of Materials

- Crystalline vs. amorphous vs. mixed systems
- Eutectic melting, glass transition, and collapse temperatures

11:00–12:00 noon: Materials Characterization Techniques

- Principles of thermal analysis – theory and equipment
- Freeze-dry microscopy equipment and techniques

1:00–1:30 p.m.: Fundamentals of Freeze-Drying – Freezing

- Ice nucleation and growth
- Eutectic and/or glass formation
- Annealing theory and techniques

1:30–2:30 p.m.: Fundamentals of Freeze-Drying - Primary Drying

- Introduction to heat and mass transfer operations
- Influence of pressure and temperature on process characteristics

3:00–4:00 p.m.: Fundamentals of Freeze-Drying - Secondary Drying

- Continuation of heat and mass transfer
- Mechanism for moisture loss and retention

4:00–5:00 p.m.: Container Closure Systems

- Influence on heat and mass transfer
- Impact of molded vs tubing vials

Second Day

8:30–9:00 a.m.: Formulation Development

- Preformulation assessment
- Selecting acceptable formulation components
- Antioxidants, stabilizers, surfactants, bulking agents, complexing agents, cosolvents

9:00–9:30 a.m.: Specialized Formulations–Biomolecules

- Biomolecule stabilization
- Infrared analysis of proteins

9:30–10:00 a.m.: Lyophilization of Cells and Modified Live Viruses

- Freezing and Drying Stresses on cells and viruses
- Cryo and Lyo preservation techniques and excipients

10:30–12:00 noon: Lyophilization Process Development and Cycle Design

- Reviewing and utilizing the thermal analysis data
- Designing an optimized freezing, primary, secondary drying protocol
- Characterizing the final dried formulation

1:00–2:30 p.m.: Understanding Pharmaceutical Freeze Dryers

- A systems approach
- Specifying a freeze dryer
- Refrigeration systems
- Redundancy

3:00–4:00 p.m.: Large Scale Industrial Freeze Dryers

- State of the art equipment
- CIP, SIP
- Stoppering
- Component configurations, bulk dryers

4:00–5:00 p.m.: Automatic Control of Freeze Dryers

- Control strategy and its evolution, degrees of automation
- Computer/PLC control of research and production freeze drying

Third Day

8:30–9:30 a.m.: Scale-Up, Cycle Transfer, and Maximum Throughput Capability

- Scale-up strategy and transfer
- Determining and preventing choked flow conditions

9:30–10:00 a.m.: Freeze-Drying in Syringes, Trays, Blister Packs, etc.

- Lyophilization of bulk materials
- Process requirements for different dosage forms

10:30–11:30 a.m.: Validation

- Quality and good business practices
- Regulatory requirements
- Validation protocols and reports requirements

11:30–12:00 noon: Lyophilization and Regulatory Compliance

- Review of applicable regulatory guidance documents
- Inspectional observations and corrective actions

1:00–2:00 p.m.: Finished Product Testing and Stability Studies

- Characterization of lyophilized products
- Detection and impact of changes over time

2:00–2:30 p.m.: Recipe Building

- Barometric Control
- Capacitance vs. Pirani

3:00–3:30 p.m.: Validation of the Freeze-Dryer, A Road Map to the Goal

- IQ/OQ
- FAT/SAT

3:30–4:30 p.m.: Operational Difficulties-Trouble Shooting

- Refrigeration, Heat Transfer, Vacuum
- Utilities, environmental considerations

4:30–5:00 p.m.: Open Discussion with Case Studies on Problem Cycles and Formulations

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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

Jeff Schwegman, Ph.D. is currently the founder and chief executive officer of AB BioTechnologies where he specializes in speaking and consulting in parenteral pre-formulation, formulation, analytical, and lyophilization of both small molecules and large biomolecules. He also holds patents and develops new technologies within the lyophilization field. Dr. Schwegman received his BS in Biochemistry from Indiana University in 1992 and began working at Cook Imaging in Bloomington Indiana, where he gained experience in analytical, formulation and process development. In 1999 he began graduate study in the Department of Industrial and Physical Pharmacy at Purdue University under the direction of Dr. Steve Nail, where his focus of research involved studying changes in the physical structure of biological molecules during lyophilization. Dr. Schwegman received his Ph.D. from Purdue University in 2003, and returned to Bloomington where he worked at Baxter Pharmaceutical Solutions as a Research Scientist in the Pharmaceutical Development group. In November 2005, he left Baxter and formed BioConvergence LLC with 3 other founders which specialized in developing new formulations and manufacturing processes for parenteral products. In February 2008, he left BioConvergence, which has become a successful company, to form AB BioTechnologies. He routinely lectures around the world on formulation, stabilization and process development of lyophilized products. He has also been an active member of AAPS since 2001.

Additional Faculty

Karen A. Bossert, Ph.D., R.Ph., Vice President, Scientific Affairs, Lyophilization Technology, Inc.

David T. Sutherland, Consultant, Lomoco

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.