Lipophilization Technology
21–22 April 2016 • Amsterdam, The Netherlands

Registration Form
Course Offering # 1604-404

Credit Card billing address (if different than above address)
__________________________________________
__________________________________________
__________________________________________

Tuition and Payment Methods

E-mail Address _______________________________________________
Tel ____________________________ Fax _________________________
City _______________________________  State _____  Zip _________
____________________________________________________________
Company/Institution __________________________________________

I accept CfPA’s Terms and Conditions

Note: Please complete separate form for each registrant.

Early Bird (Save $200)
( Must register and pay by 10 March 2016)
U.S.$ 1870 pp

Regular Tuition
U.S.$ 2070 pp

Group Discount: Register 2 or more from the same company, at the same time, for this course and receive a 10% discount off each registration.
Tuition payable in U.S. funds net of all charges. Includes continental breakfast, luncheon, breaks and course notes.

Note: Payment is due 2 weeks prior to course or at time of registration.

Who We Are

The Center for Professional Advancement (CfPA) is the largest accredited technical training organization in the world with a curriculum of approximately 450 short courses in 15 industries including Pharmaceutical, Biotechnology, Medical Device, Chemical, Cosmetics, Food and more.

Accreditations/Recertifications

The American Society for Quality (ASQ)
Recertification Opportunities
The following information was provided courtesy of ASQ, and is not meant as an endorsement of CfPA courses. It serves only as an informational guide about the certifications offered by ASQ. Many CfPA courses offer training that may be helpful in obtaining required ASQ recertification education units. To view a list of recommended courses that may be appropriate please visit www.cfpa.com.

For more information about ASQ, contact them at: help@asq.org

Tuition payable in U.S. funds net of all charges. Payment is due at time of registration or upon receipt of invoice. 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-Bird tuition rate, payment is required at time of registration and/or BEFORE early registration tuition expires or the regular tuition rate will apply. If choosing invoice/ wire transfer, payment must be received prior to expected date of invoice. If you do not cancel and do not attend you are still responsible for the full payment.

Cancellations/Substitutions/FEES: ALL cancellations must be in writing and emailed to: info@cfpa.com. All cancellations are subject to a $300.00 cancellation fee. Applicants may cancel up to four (4) weeks prior to the course start date for a refund less cancellation fee. Applicants that cancel less than four (4) weeks prior to the course will be issued a credit less cancellation fee that can be used towards a future course up to one year from the date of issuance. If you do not cancel and do not attend you are still responsible for the full payment. 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. Substitutions are permitted at any time, must be in writing and emailed to Customer Service at info@cfpa.com.

Confirmation Letters: Before each course begins, all registrants will receive written final confirmation including detailed information regarding course location – VA 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 at info@cfpa.com.

Course photography / video: By registering and attending a CfPA course, you agree to have your photograph and/or video taken at the course venue, and you do not have any objections to CfPA using these photos and/or videos for marketing or any other CfPA Course and/or promotional purposes. You agree to release CfPA from any kind of claims arising out of copyright or privacy violations. All questions regarding this matter should be sent to Customer Service at info@cfpa.com.

Courses of Interest

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Since our founding in 1967, we have successfully trained nearly a half million people worldwide in topics ranging from basic and introductory courses to the latest 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.

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Lyophilization Technology

Course Outline

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First Day

08.00: Registration
08.30–09.00: Review of Learning Objectives
• Course introduction and format
09.00–10.00: Introduction to Freeze-Drying
• Basic theory and brief history
10.15–11.00: Physical Properties and Characterization of Materials
• Crystalline vs. amorphous vs. mixed systems
• Eutectic melting, glass transition, and collapse temperatures
• Principles of thermal analysis – theory and equipment
• Freeze-dry microscopy equipment and techniques
11.00–12.00: Fundamentals of Freeze-Drying – Freezing
• Ice nucleation and growth
• Eutectic and/or glass formation
• Annealing theory and techniques
12.00–13.00: Lunch/Short Break
13.00–14.00: Fundamentals of Freeze-Drying – Various stages
• Primary drying: Introduction to heat and mass transfer operations
• Influence of pressure and temperature on process characteristics
• Secondary drying: Mechanism for moisture loss and retention
• End of drying: Determination of termination of cycles
13.30–16.00: Container Closure Systems
• Influence on heat and mass transfer: Impact of molded vs tubing vials
• Container closure qualifications: Container-closure operational qualification (CCOQ), Container-closure integrity testing (CCIT), Delamination issues, via breakage etc.
16.00–17.00: Formulation Development – Small and Large Molecules
• Pre-formulation assessment
• Selecting acceptable formulation components
• Examples

Second Day

08.30–09.30: Lyophilization Process Development and Cycle Design
• Reviewing and utilizing the thermal analysis data
• Designing optimized freezing, primary, and secondary drying regimens
09.30–10.15: Quality Control of Lyophilized products
• Finished product testing
• Appearance of cake, moisture content, other inspection issues
• Stability tests
10.30–12.00: Scale-Up and Cycle Transfer, Maximum Throughput Capability
13.00–14.00: Understanding Pharmaceutical Freeze Dryers
• Components of a freeze dryer
• Measurement/Control systems
• CIP, SIP, Stoppering; Automated loading
• Computer/PLC control of research and production freeze drying
14.00–15.00: Other considerations
• Non-aqueous lyophilization, controlled nucleation, vacuum in vials, bulk freeze drying, remote sensing of product temperatures
• Syringe Freeze-drying
• Review of some representative freeze drying cycles
• Some significant publications
15.15–16.00: Validation and regulatory aspects
• Regulatory requirements, QbD Principles
• Validation of the Freeze-Dryer
• IQ/OQ, FAT/SAT
• Regulatory Compliance: Review of applicable regulatory guidance documents, Inspectional observations and corrective actions
16.00–17.00: Review of the course
Assessment Opportunity

Who Should Attend

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

• R & D Personnel
• Pilot Plant Operations
• Production Supervisors
• Managers
• Pharmacists
• QA/QC
• Regulatory Affairs

Who Should Attend:

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:

• Outline the fundamentals of lyophilized product development and the underlying scientific and engineering principles involved in freezing, primary drying and secondary drying
• Explain the requirements needed to develop efficient freeze-drying cycles
• List the factors involved in process scale-up, control and optimization
• Describe the equipment and instrumentation involved in lyophilization
• Explain the requirements for validation of lyophilization processes and products
• Discuss recent trends in lyophilization of pharmaceuticals

Course Description

This course presents the principles and techniques of lyophilization based on theoretical concepts and practical examples. Scientific aspects of aqueous systems, phase transitions, collapse phenomena are explained. Emphasis on pharmaceutical aspects including formulation, stability, cycle development, process scale-up and analytical instrumentation is provided. Regulatory requirements including cGMPs, validation and qualification will be discussed. Engineering elements of heat and mass transfer, process control, and lyophilizer qualification are reviewed as well. The principles presented will be related to practical industrial examples throughout the course.

Course Director

Dr. Madhav Kamat is a Founder/CEO of Kamat Pharmatech LLC, a pharmaceutical consultancy firm, having 25 years of sound industrial experience specializing in the area of injectable products and processes. Dr. Kamat has a significant experience in product/process development (small molecule and biologicals) involving formulation development, lyophilization, scale-up/technology transfer, and sterile manufacturing of more than 20 injectable products. He is well recognized for his expertise in the lyophilization, nanosuspension technology, aseptic technology, and other sterile manufacturing processes. His recent interests are formulation and process development of biological products and IV injectable products of water insoluble drugs. Dr. Kamat received his B. Pharm and M. Pharm from Bombay University and Ph.D. from the College of Pharmacy at University of Kentucky, USA. Dr. Kamat’s Ph. D. dissertation was based upon lyophilization technology, and he has authored many publications on sterile products and lyophilization. Dr. Kamat worked at Bristol Myers Squibb Company for the last seventeen (17) years in Technical Operations and R&D—most recently as a Director. Prior to BMS, Dr. Kamat worked at Centocor Inc. and Johnson & Johnson. Dr. Kamat has been a visiting professor at the College of Pharmacy, University of Kentucky and at New Jersey Institute of Technology, NJ. Dr. Kamat is also a Registered Pharmacist in the States of Pennsylvania and New Jersey.

Additional Faculty

Mukund ‘Mike’ Yelvigi, Founder & Principal at Center for Pharmaceutical Integration, LLC, New Jersey

Course Location

This course will be held in the Amsterdam 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 arrangements not be made until final confirmation package is received.

• Located in downtown area, near shopping, dining and local attractions

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.

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