



CfPA

The Center for Professional Advancement

Accredited Technical Training Worldwide

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ON-DEMAND Online Training Course Lyophilization: Optimized Pre-Formulation, Formulation, and Cycle Development Techniques

Location: Your Computer

Offering # 0811-703

Priority Code: 520

WHO SHOULD ATTEND

This course is designed for personnel in the pharmaceutical, diagnostic, biomedical engineering and biotechnology industries including:

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

LEARNING OBJECTIVES

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

- Discuss specific characteristics important for the pre-formulation development stage of Lyophilization
- Explain the critical properties in formulation development
- Discuss the critical properties in optimized lyophilization cycle development protocol and finished product characterization

COURSE DESCRIPTION

This 90-minute **accredited** online course is designed to provide an introduction to the basic scientific principles of conducting optimized pre-formulation, formulation and cycle development studies for products requiring lyophilization. This course will provide insight into determining and then designing the optimal conditions for the molecule of interest through targeted pre-formulation and formulation studies. Insight will then be provided into the process of developing an optimized lyophilization cycle around that formulation.

By understanding the specific characteristics of the molecule of interest through pre-formulation and formulation development studies, the development scientist will be able to develop robust, stable formulations and lyophilization cycles in a much more efficient manner, in addition to being able to troubleshoot

Module 1:

Pre-Formulation Development

- Developing a pH Stability Profile
- Developing a pH Solubility Profile
- Conducting a Cosolvent Solubility Screen
- Determining Thermal Stability
- Determining Light Stability
- Determining Oxidation Potential
- Specialized Studies for Bio-Molecule Formulations

Module 2:

Formulation Development

- Designing a Buffer System
- Solubility Enhancement
- Choosing Bulking Agents
- Evaluating Stabilizers
- Conducting Accelerated Stability Studies
- Evaluating Container Closure Systems

Module 3:

Lyophilization Cycle Development

- Developing an Optimized Freezing Protocol
- Developing an Optimized Primary Drying Protocol
- Developing an Optimized Secondary Drying Protocol
- Determining if an Annealing Step is Necessary and Designing One Correctly
- Conducting Solid State Characterization of the Finished Product

Question and Answer Session

COURSE DIRECTOR

J. Jeff Schwegman Ph.D., Founder/CEO AB BioTechnologies

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.

REGISTRATION

TUITION* - **Single Rate: U.S. \$99.00 per person** **Group Rate: U.S. \$99.00 per person****

Register at www.cfpa.com. Enter **Course Offering #0811-703** into **Quick Jump**. To register use **Priority Code: 520**.

For Questions and Information call Customer Service at 732-613-4500.

Please Note: Multiple participants are not authorized to share access provided to a single registrant, a single dedicated seat license must be purchased for each individual. CfPA reserves the right to cancel access or collect the group rate payment if this requirement has been violated.

ABOUT ON-DEMAND:

Our pre-recorded on-line training courses are available for viewing at your convenience at your computer. Register for a CfPA on-demand course, your registration will be processed within two (2) business days, after payment and registration are complete you will receive an email from olinettraining@cfpa.com with your password to access the on-demand course. You will have two (2) business days to view the course. You **MUST** complete all polls and the course evaluation to receive your accreditation certificate for this course.

TERMS AND CONDITIONS

***Payment:** Tuition payable in US funds net of all charges. Payment is due at time of registration in the form of a credit card. Please contact CfPA's Customer Service for other payment options.

****Group Rate:** The Group Rate is for two or more enrollments, up to five registering from the same company at the same time. For groups of six or more, please contact Customer Service for group pricing. **Cancellations/No Show: "Live"**- Registrants may cancel up to two working days prior to the course start date and will receive a letter of credit to be used towards a future course up to one year from date of issuance. No credit will be issued for no-shows and/or cancellations less than two working days prior to the course. : **"On-Demand"**- No refund or credit will be issued for no-shows and/or cancellations of on-demand training courses. CfPA is not responsible for any outside related costs incurred by registrant's cancellation.