

Registration Information

Registration Form

Name: _____
Company: _____
Address: _____
City: _____ State: _____ Zip: _____
Country: _____ Telephone: _____
Fax: _____ Email: _____

How did you hear about this course: Received a brochure in the mail Colleague E-mail Web site Online Search Engine Other _____

Method of Payment (\$1,495 per person)

Check Money Order Purchase Order
 Visa/MC American Express
Credit Card or P.O. Number: _____
Name on Credit Card: _____
Credit Expiration Date: _____

Register Early. Class size will be limited !!!

Course Venue

Fundamentals of Protein Pharmaceutical Formulation Development will be held at the Millennium Bostonian Hotel in Boston, MA. The hotel is located in the heart of downtown Boston, across the street from Faneuil Hall and a short walk from Boston's historic North End and waterfront. **A block of rooms has been reserved for this course. Please call McAfee Consulting for assistance with booking your room.**

www.millenniumhotels.com

Five Easy Ways to Register!

Phone: (817) 483-4126 **Fax:** (817) 483-7574

On line: www.prochemist.com

Email: register@prochemist.com

Mail: McAfee Consulting
P.O. Box 36
Kennedale, TX 76060

Make Checks Payable to: **McAfee Consulting**

Pharmaceutical Development Course www.prochemist.com

Fundamentals of Protein Pharmaceutical Formulation Development



October 11-12, 2007
Millennium Bostonian Hotel • Boston, MA

Course Instructors:

Bret A. Shirley, Ph.D.
Director of Pharmaceutical Sciences
Stryker Biotech

Janet Wolfe, Ph.D.
Founder & CEO
Wolfe Laboratories

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Helping You Bridge Discovery and Development

Presented by McAfee Consulting

Fundamentals of Protein Pharmaceutical Formulation Development

October 11-12, 2007
Boston, MA

Course Description

Protein therapeutics present significant challenges to the development of stable, commercially viable pharmaceutical formulations. Proteins degrade by multiple mechanisms, and each molecule presents unique challenges that must be appropriately understood and addressed during the formulation development process. Fundamentals of Protein Pharmaceutical Formulation Development is designed to impart to you the tools and knowledge necessary to systematically approach the development of therapeutic protein formulations.

The course will detail **formulation development requirements** within the context of each phase of the clinical development process, with the ultimate goal of a robust, stable, user-friendly commercial product. An **overview of protein structure** will be given with special emphasis on its relationship to protein **chemical and physical degradation pathways**. Formulation studies appropriate for each phase of pre-clinical, clinical and commercial development will be presented. **Protein analytical methods** will be detailed, along with their proper use during each phase of formulation development. Case studies will be used to illustrate important aspects of **protein formulation, stability and characterization** to allow you to gain firsthand knowledge of solutions to real-world challenges in the development of protein pharmaceutical formulations.

Who Should Attend?

This course is designed for **Pharmaceutical Industry personnel involved in the design and development of formulations for therapeutic proteins.**

- Pharmaceutical Chemists
- Protein Chemists
- Bioanalytical Chemists
- Biochemists
- Members of R&D
- Project Management
- Manufacturing
- Quality Control
- Quality Assurance
- Regulatory Affairs

Course Instructors

Bret A. Shirley, Ph.D.



Bret Shirley is currently the Director of Pharmaceutical Sciences at Stryker Biotech (Hopkinton, MA) where he has responsibility for the development of formulations, drug delivery systems and analytical methods. Prior to his current position, he held positions at Altus Pharmaceuticals, Syntonix Pharmaceuticals, the Chiron Corporation and Boehringer Ingelheim Pharmaceuticals. Dr. Shirley has over 15 years of experience in the development of formulations for therapeutic proteins. He received a doctorate in Protein Biochemistry from Texas A&M University.

Janet Wolfe, Ph.D.



Janet Wolfe is founder and CEO of Wolfe Laboratories and the WXYZ Group, a family of contract research and development groups located in Watertown, Massachusetts. Prior to starting Wolfe Laboratories, Dr. Wolfe was on the faculty of the department of Pharmaceutical Sciences at the University of Tennessee, Memphis. Dr. Wolfe has over 15 years experience in pharmaceutical research and development and is the author of numerous articles and presentations. She received a doctorate in Pharmaceutical Chemistry from the University of Kansas.

Discounted Registration!

- ⇒ Send 2 full price attendees from the same institution, and get the 3rd at half price
- ⇒ Send 3 full price attendees from the same institution, and the 4th is free!

Key Benefits of Attending

- Explore the formulation development challenges unique to therapeutic protein products
- Learn systematic approaches to the development of liquid and lyophilized protein formulations
- Gain insight into state of the art analytical methods used to characterize proteins and to assess protein stability
- Discover how to identify and characterize protein degradation pathways early in the formulation development process to maximize your chances of success
- Evaluate forced degradation studies to accelerate your formulation development efforts
- Learn to design and conduct appropriate formulation and stability studies to support each phase of product development
- Review formulation development case studies from real-world protein therapeutic products
- Discuss your particular formulation development challenges with instructors during and after the course.

Join us for a Taste of Boston
reception on the first evening of
the course!

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