

# Registration Information

## Registration Form

Name: \_\_\_\_\_  
Company: \_\_\_\_\_  
Address: \_\_\_\_\_  
City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_  
Country: \_\_\_\_\_ Telephone: \_\_\_\_\_  
Fax: \_\_\_\_\_ Email: \_\_\_\_\_

**How did you hear about this course:**  Brochure via mail  
 Colleague  E-mail  Web site  Online Search Engine  
 Other \_\_\_\_\_

### Please register me for:

- San Francisco (April 24 & 25, 2008) - code 0108S
- Boston (May 15 & 16, 2008) - code 0108B

### 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: \_\_\_\_\_  
Signature: \_\_\_\_\_

**Register Early. Class size will be limited !!!**

## Course Venues

**San Francisco** — **Fisherman's Wharf Hilton**, located in San Francisco's historic Fisherman's Wharf, is convenient to shopping and major attractions such as the Golden Gate Bridge, China Town and North Beach. **Phone: 415-885-4700**

**Boston** — **Back Bay Hilton**, in the heart of Boston's picturesque Back Bay district, is conveniently located near major attractions including the Boston Common, Newbury Street, Fenway Park and the historic North End. **Phone: 617-236-1100**  
**A limited block of rooms has been reserved at each hotel at a special discounted rate. Please contact the hotel directly to book your room.**

[www.hilton.com](http://www.hilton.com)

### Five Easy Ways to Register!

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

**On line:** [www.prochemist.com](http://www.prochemist.com)

**Email:** [register@prochemist.com](mailto: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](http://www.prochemist.com)

# Fundamentals of Protein Pharmaceutical Formulation Development



**April 24-25, 2008**  
**Fisherman's Wharf Hilton**  
**San Francisco, CA**

**May 15-16, 2008**  
**Back Bay Hilton**  
**Boston, MA**

Sponsored by  
**Wolfe**  
Laboratories

Helping You Bridge Discovery and Development

Presented by McAfee Consulting

# Fundamentals of Protein Pharmaceutical Formulation Development

## 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 Senior 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, located in Wattertown, 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 challenges unique to the development of formulations for therapeutic protein products.
- 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 reception on the first evening of the course!



Helping You Bridge Discovery and Development