

# 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 0208S  
 Boston (May 15 & 16, 2008) - code 0208B

### 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 adjacent to 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, 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 Solid Oral Dosage 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 Solid Oral Dosage Formulation Development

## Course Description

As our understanding of target receptors increases, small drug candidates (MW <1,000) are becoming ever more complex, often possessing low water solubility and poor chemical and/or physical stability. These physico-chemical properties present significant challenges to those involved in the product development of new molecular entities. Each molecule represents unique challenges that must be understood and addressed during the formulation development process, and rigorous preformulation studies are the cornerstone of successful drug product development. **Fundamentals of Solid Oral Dosage Formulation Development** is designed to impart to you the tools and knowledge necessary to ensure that these molecules move rapidly and seamlessly from discovery through the various stages of product development to commercial manufacturing.

The course will provide an overview of the **Biopharmaceutics Classification System** and the impact of physico-chemical properties on formulation strategies at each stage of development. Methods of **solid state characterization and preformulation studies** needed to select the most appropriate physical form and lay the foundation for formulation development will be discussed in detail. **Strategies for rapid development** of first in human formulations, as well as formulation studies for each phase of development, will be presented. **Analytical methods utilized for both drug substance and drug product** will be detailed along with required **stability studies and specifications** appropriate for each phase of development. Case studies will be used to illustrate the **importance of physico-chemical properties in the selection of the most suitable physical forms (polymorph, salt, etc.) and proper dosage form selection** to allow development of stable, bioavailable and manufacturable drug products.

## Who Should Attend?

- Pharmaceutical Chemists
- Discovery Chemists
- Bioanalytical Chemists
- Pharmaceutical Analysts
- Members of R&D
- Project Managers
- Manufacturing
- Quality Control
- Quality Assurance
- Regulatory Affairs

## Course Instructors

### Shelley R. Rabel, Ph.D.



Shelley Rabel is the Vice-President of Riley & Rabel Consulting Services, LLC. Prior to her present position, she held positions at DuPont Merck, DuPont Pharmaceuticals, ALZA (a subsidiary of J&J), and Amgen. She has over 12 years of experience in the pharmaceutical industry in small molecule preformulation and formulation support for Discovery and Pharmaceutical Development groups, as well as experience in the formulation development and manufacture of controlled-release dosage forms. Dr. Rabel has 19 publications and three patents. She received a doctorate in Pharmaceutical Chemistry from the University of Kansas.

### Christopher M. Riley, Ph.D.



Christopher Riley is President of Riley & Rabel Consulting Services, LLC. Prior to his current position, he held faculty positions in the Departments of Pharmaceutics, University of Florida and Pharmaceutical Chemistry, University of Kansas; Vice President of Analytical R&D at DuPont Merck, DuPont Pharmaceuticals (now BMS), and Vice President and West Coast Site Head of ChemPharm Development for J&J. He has over 25 years experience in pharmaceutical sciences and drug product development. He has more than 100 book chapters and papers, as well as two books. He received a doctorate in Pharmaceutical Chemistry from the University of Bath, England.

### Janet Wolfe, Ph.D.



Janet Wolfe is founder and CEO of Wolfe Laboratories, 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 challenges of developing new molecular entities for oral delivery.
- Gain understanding of preformulation studies required to lay scientific foundation for small molecule formulation development.
- Learn to design and conduct formulation development studies to allow development of stable, bioavailable and manufacturable drug products for each stage of development.
- Gain insight into state of the art analytical methods used to characterize drug substance and drug product.
- Learn to design stability studies and develop specifications to support product development.
- Review formulation case studies and propose strategies and approaches to product development.
- Interact with course instructors and peers in the pharmaceutical and biotechnology industries to discuss real world formulation issues.

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

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