

# Drug Development Briefing

**Date:** June 17, 2012

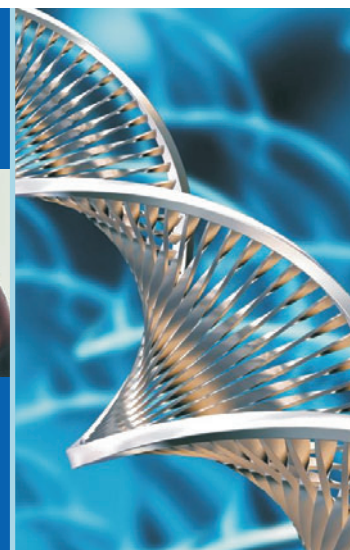
**Time:** 9:00am - 4:30pm

**Fee:** \$395 *Special BIO2012 Rate*

**Location:** Westin Boston Waterfront Hotel  
425 Summer Street • Ballroom C  
Boston, MA 02210



BIO2012 Affiliate Program



**Register Today:** Pre-registration required. No registration day of class. No walk-ins.

## Schedule

### Drug Development Overview 9:00 –10:00

- Success Metrics
- Chances of Success
- Timelines & Costs
- Scientific Milestones
- Go/No Go Decisions

### Origin of New Drugs 10:00 –10:50

- Plants, Animals & Laboratories
- Rational Drug Design & Targets
- Combinatorial Chemistry
- Alliances
- Start-Ups

### Break 10:50 –11:00

### Selecting Drug Candidates 11:00–11:45

- Chemistry
- Drugability
- Early Toxicology
- Pharmacology
- ADME

### Target Product Profile 11:45 –12:15

- Draft Label
- Commercial Evaluation
- Exclusivity & Patents
- Waxman Hatch

### Lunch 12:15 –1:00

### The Regulatory Process 1:00 –1:45

- History of Regulation
- Initial New Drug Application (IND) & Clinical Trial Application (CTA)
- FDA, European Medicines Agency (EMA) & International Conference on Harmonization (ICH)
- New Drug Application (NDA), Marketing Authorization Application (MAA) & Common Technical Document (CTD)
- Clinical Holds
- Quality Assurance
- Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP) & Good Clinical Practices (GCP)

### Drug Development Pre-IND 1:45 – 2:30

- Chemistry, Manufacturing & Controls (CMC)
- Characterization, Purity & Stability
- Formulation
- Preclinical

### Break 2:30 – 2:45

### Clinical Development 2:45 – 4:15

- Clinical Trial Considerations
- Design, End Points & Statistics
- Phase 1
- Phase 2a & 2b
- Phase 3a & 3b
- Phase 4
- Safety
- Pharmacogenomics
- Risk Management Plan

### Q&A/Review 4:15 – 4:30

## Course Description

Participants learn the scientific decisions involved in moving a product forward from basic research into preclinical and clinical trials, as well as a detailed consideration of the regulatory requirements of clinical development.



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### Deliverables:

A workbook including all slides presented in the course, "Take Home Points" for each slide, and a list of common drug development acronyms. A certificate of completion will be issued at the end of the class. Lunch will be provided.

### Refunds:

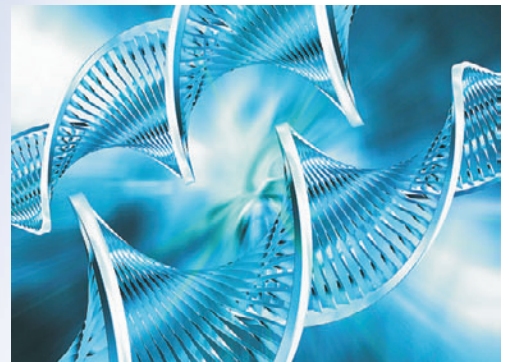
Refunds are not given. Registrants may not switch classes. If a registrant cannot attend, someone from their organization may take their place. Please contact Kerri Muir with substitute name and contact information.

### Questions?

Contact Kerri Muir at 410.377.4429 x22 or [Muir@BiotechPrimerInc.com](mailto:Muir@BiotechPrimerInc.com)

### To Register:

[www.BiotechPrimerInc.com](http://www.BiotechPrimerInc.com) and click on "Class Registration".



### Instructor: Simon J. Tulloch, MD

Dr. Tulloch has more than 25 years of pharmaceutical and biotech experience in clinical development, R&D management, and business roles, both in Europe and the USA. He consults to the industry on strategic R&D issues, clinical development and medical issues. He has been the Chief Medical Officer at InfaCare Inc, a privately funded biotech company, and spent ten years at Shire Pharmaceuticals. He moved to the USA to establish Shire's U.S. research and development organization. Dr. Tulloch built the organization in all areas of drug development, and successfully conducted the development and NDA approval of Adderall XR. During that time his organization also developed and got NDA approvals for Fosrenol (Shire's first global NCE) and Equetro, as well as providing CMC, preclinical, and marketing medical support to all of Shire's U.S. products. Latterly, he assumed the role of head of the global CNS Business Unit.

Prior to his time at Shire, Dr. Tulloch spent eight years with Johnson & Johnson companies, including five years as clinical research director for R.W. Johnson PRI's European R&D facility in Zurich, Switzerland, working on multiple projects in various therapeutic areas and stages of development. He trained in medicine at Oxford University, has a degree in physiology and a diploma in pharmaceutical medicine, and worked for a number of years for the UK National Health Service in hospital posts.



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