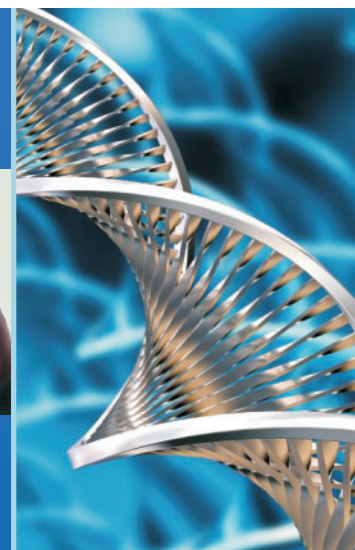


Drug Development Briefing

Date: May 4, 2012
Time: 9:00am - 4:30pm
Fee: MassBio Members \$795
Non-Members \$945
Location: MassBio Offices
300 Technology Square • 8th Floor
Cambridge, MA 02139



Schedule

Drug Development Overview 9:00 – 10:00

- Success Metrics and Chances of Success
- Timelines and Costs
- Milestones
- Go/No-Go Decisions
- Integrated and Global Development

Origin of New Drugs 10:00 – 11:00

- Plants, Animals and Laboratories
- Rational Drug Design and Targets
- Combinatorial Chemistry
- Alliances
- Start-ups

Break 11:00 – 11:15

Selecting Drug Candidates 11:15 – 11:45

- Macro Commercial Input
- Market Dynamics
- Chemistry
- Drugability
- Early Toxicology
- Pharmacology
- ADME*

Target Product Profile 11:45 – 12:15

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

Lunch 12:15 – 1:00

The Regulatory Process 1:00 – 1:45

- History of Regulation
- IND* and CTA*
- FDA, EMEA* and ICH*
- NDA*, MAA* and CTD*
- Clinical Holds
- Quality Assurance
- GMP*, GLP* and GCP*

Drug Development Pre-IND 1:45 – 2:30

- CMC*
- Characterization, Purity and Stability
- Formulation
- Preclinical

Break 2:30 – 2:45

Clinical Development 2:45-4:15

- Clinical Trial Considerations
- Design, End Points and Statistics
- Phase 1
- Phase 2a and 2b
- Phase 3a and 3b
- Phase 4
- Safety
- Pharmacoeconomics
- Life Cycle Management
- Risk Management Plan

Wrap-Up 4:15 – 4:30

- Review
- Evaluations

Course Description

Drug Development Briefing delivers an overview of the discovery, development, and regulatory processes for bringing a new drug (large & small molecule) to market. Participants learn about the business and 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. Post-approval commercial considerations and risk management are also discussed.



*ADME: Absorption, Distribution, Metabolism & Excretion; *IND: Initial New Drug Application; *CTA: Clinical Trial Application; *EMA: European Medicines Evaluation Agency; *ICH: International Conference on Harmonization; *NDA: New Drug Application; *MAA: Marketing Authorization Application; *GMP: Good Manufacturing Practices; *GLP: Good Laboratory Practices; *GCP: Good Clinical Practices; *CMC: Chemistry, Manufacturing & Controls; *CTD: Common Technical Document

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:

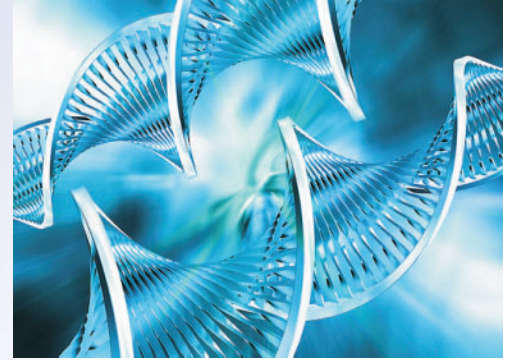
Refunds are not given. Registrants may not switch classes. If a registrant cannot attend, someone from their organization may take their place. Please contact Kerri Muir with substitute name and contact information.

Questions?

Contact Kerri Muir at 410.377.4429 x22 or Muir@BiotechPrimerInc.com

To Register:

www.BiotechPrimerInc.com and click on "Class Registration".



Instructor:

Simon J. Tulloch, M.D.

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.

