

Applying Pharmacokinetics and Pharmacodynamics for Regulatory Submissions

Course # T39

November 03 - November 04, 2010

Start - 8:00 Finish - 5:00

Hotel Information:

[Hyatt Arlington](#)

Hyatt Arlington

1325 Wilson Boulevard

Arlington, VA 22209

(703) 525-1234

Rate: \$

Deadline for Group Rate:

[Hotel Policy](#)

Registration Rate:

\$1,495.00 Register by 09/20/10

\$1,695.00 Register after 09/20/10

Cancellation Date: 10/25/10 (Cancellation fee is determined by date cancelled.)

[Register Now](#)

[Registration Policy](#)

Continuing Education Credit:

ACPE: 0708-0000-10-040-L03-P (1.4 CEU)

Initial Release Date: 11/3/10

CBRN: N/A

CME: 14 Hours of Category 1 Credit

VNA: 07-04-01 14 Contact Hours

[Continuing Education Policy](#)

Course Description:

This course will be held at:

The PERI Training Facility

1616 N Fort Myer Drive Suite 1430

Arlington, VA 22209

Day 1: 8:00 AM - 5:00 PM

Day 2: 8:00 AM - 5:00 PM

This course, taught by industry and FDA faculty, provides strategies for meeting biopharmaceutical and clinical pharmacology/pharmacokinetic requirements from the IND to the NDA.

Emphasis will be on the studies needed to successfully file an IND and NDA from the Clinical Pharmacology perspective. Various topics such as bioanalysis, biopharmaceutics, bioequivalence, drug disposition, PK in special populations, pharmacogenomics and pharmacometrics will be covered.

Who Should Attend:

This course is intended for those who work primarily in PK, and for those primarily responsible for regulatory filings (regulatory affairs, clinical). FDA Reviewers and other personnel will also benefit from this course.

Educational Objectives:

Upon completion of this course, participants should be able to:

- Define method validation techniques for bioanalysis
- Apply concepts of BCS to interpretation of biopharmaceutical studies
- Understand characterization of drug disposition and drug-interaction potential
- Discuss the importance of pharmacogenomics and pharmacometrics
- Identify key features of Thorough QT Study (TQTS)
- Apply strategies learned in the program to successfully submit the Clinical Pharmacology section of an NDA

Key Topics:

- Pharmacokinetic Concepts
- Bioanalysis
- Biopharmaceutics
- Bioequivalence
- Characterizing metabolism and excretion
- Drug-drug interaction studies
- PK in special populations
- Pharmacogenomics
- Pharmacometrics
- Biologics
- QTc
- Content and format of the Clinical Pharmacology (CP) section of an NDA

Course Director(s):

Punit H Marathe, PhD

Director, Metabolism and Pharmacokinetics

Bristol-Myers Squibb