

“PRINCIPLES OF CLINICAL PHARMACOLOGY” COURSE**2015-2016 SCHEDULE**

**All sessions will meet Thursday evenings from 6:30 p.m. to approximately 7:45 p.m.
in the NIH Clinical Center, Building 10, in the Lipsett Amphitheater in Bethesda, Maryland.
Course Web Site: <http://pcp.nihtraining.com>**

MODULE 1: PHARMACOKINETICS:

September 3rd	Introduction to Clinical Pharmacology and Pharmacokinetics Clinical Applications of Pharmacokinetics	J. Lertora (NIH-CC)
September 10th	Compartmental analysis of drug distribution	J. Lertora (NIH-CC)
September 17th	Chemical assay of drugs and drug metabolites	S. Markey (NIST)
September 24th	Use of positron emission tomography (PET) in pharmacokinetics	R. Innis (NIH-NIMH)
October 1st	Drug absorption and bioavailability	J. Lertora (NIH-CC)
October 8th	Effects of renal disease on pharmacokinetics	J. Lertora (NIH-CC)
October 15th	SPECIAL LECTURE: Pharmacokinetics in patients requiring renal replacement therapy	A. Atkinson (Northwestern Univ.) and G. Susla (MedImmune, Inc)
October 22nd	Noncompartmental vs. compartmental approaches to PK analysis	P. Vicini (MedImmune, Inc)
October 29th	Effects of liver disease on pharmacokinetics	J. Lertora (NIH-CC)
November 5th	Population pharmacokinetics	R. Miller (Daiichi Sankyo, Inc.)

MODULE 2: DRUG METABOLISM AND TRANSPORT:

November 12th	Pathways of drug metabolism	S. Markey (NIST)
November 19th	Biochemical mechanisms for drug toxicity	A. Beasley Green (NIST)
December 3rd	Pharmacogenomics	D. Flockhart (IUPUI)
December 10th	Drug Interactions	S. Robertson (Vertex Pharmaceuticals Inc)
December 17th	Equilibrative and concentrative drug transport	J. Ware (Genentech, Inc.)
January 7th	SPECIAL LECTURE: P-glycoprotein and drug transport	M. Gottesman (NIH-OIR) and M. Hall (NIH-NCI)

MODULE 3: ASSESSMENT OF DRUG EFFECTS:

January 14th	Dose response and concentration response analysis	J. Lertora (NIH-CC)
January 21st	Physiological and laboratory markers of drug effect	J. Woodcock (FDA-CDER)
January 28th	Disease progression models and clinical trial simulation	D. Mould (Projections Research, Inc.)

MODULE 4: OPTIMIZING AND EVALUATING PATIENT THERAPY:

February 4th	Clinical analysis of adverse drug reactions	C. Chamberlain (FDA-CDER)
February 11th	Developmental and pediatric pharmacology	J. van den Anker (Children's National Medical Center)
February 18th	Drug therapy in pregnant and nursing women	C. Stika (Northwestern Univ.)
February 25th	Drug therapy in the elderly	D. Abernethy (FDA-CDER)
March 3rd	Quality assessment of drug therapy	C. Daniels (UCSD)

MODULE 5: DRUG DISCOVERY AND DEVELOPMENT:

March 10th	Drug discovery	E. Sausville (Univ. of Maryland Medical System)
March 17th	Nonclinical drug development	C. Takimoto (Centocor R&D, Inc./Johnson & Johnson)
March 24 th	Animal scale up and Phase I studies	J. Collins (NIH-NCI)
March 31st	Development and applications of cell based therapies	D. Stroncek (NIH-CC)
April 7th	Development of biotechnology products and large molecules	P. Garzone ((Pfizer, Inc.)
April 14 th	Design of clinical drug development programs	C. Breder (FDA-CDER)
April 21nd	Role of the FDA in guiding drug development	C. Peck (CDDS, UCSF)