

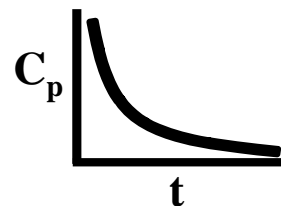
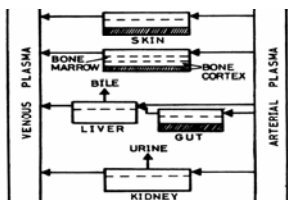
PB

MECHANISTIC & PHYSIOLOGIC

PK

PHARMACOKINETICS

Concepts and Applications



COURSE OUTLINE

Purpose: Do you apply noncompartmental pharmacokinetic modeling and wish for more substance? Do you fit data with compartmental models and seek more mechanistic and physiologic insights into the determinants of drug disposition? Do you need better understanding of how to translate preclinical measurements into clinical PK relevance? This course will assist those performing basic pharmacokinetic calculations to move towards in-depth understanding on how the physicochemistry of molecules interact with the biochemical and physiologic functions of mammalian systems to create unique pharmacokinetic properties.

Faculty from the Department of Pharmaceutical Sciences at the University of Buffalo have provided world leadership in academic instruction and laboratory training in pharmacokinetics and pharmacodynamics for over fifty years. They have adapted their graduate coursework into lucid tutorials which will allow novice modelers to gain an appreciation of how and why diverse molecules are handled by the body. Providing clarity on what to measure, meaningfulness of calculated parameters, and prediction of PK are our goals.

This course presents concepts and applications, but not hands-on data fitting, although computer code will be provided for many of the major models and some practical exercises will be discussed.

Donald E. Mager, PharmD, PhD

COURSE DIRECTION

William J. Jusko, PhD

Dr. Mager is Associate Professor of Pharmaceutical Sciences at the University at Buffalo. He has been a fellow of the American Foundation for Pharmaceutical Education and received the New Investigator Award in Pharmacokinetics, Pharmacodynamics, and Drug Metabolism from the AAPS in 2007. Dr. Mager serves as Visiting Professor at the Université Paris Descartes and on the Advisory Committee on Clinical Pharmacology to the FDA. His research invokes PK/PD systems analysis to characterize drug effects, with particular interest in anti-cancer and immuno-modulatory pharmacotherapy.

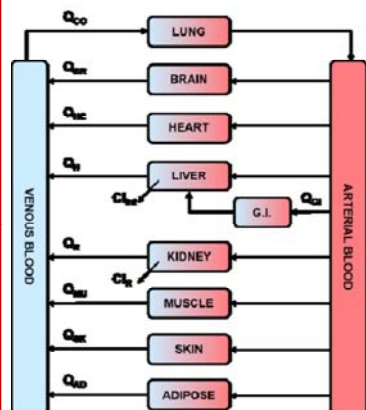


Donald E. Mager, PhD

Dr. Jusko is SUNY Distinguished Professor and Chair of Pharmaceutical Sciences at the University of Buffalo and Director of the Center of Excellence in Pharmacokinetics and Pharmacodynamics. Dr. Jusko supervises a research program on the pharmacokinetics and pharmacodynamics of immunosuppressive, antidiabetic, and anticancer drugs. He holds two NIH grants in the areas of corticosteroid PK/PD and mathematical modeling. He has authored over 560 publications, consults for the FDA, NIH, and the pharmaceutical industry, and is listed in ISI Most Highly Cited in Pharmacology.



William J. Jusko, PhD



Ancillary Course

June 17-19, 2013

PK/PD Modeling

Dr. William Jusko
& Faculty
Dept. of Pharmaceutical
Sciences

University at Buffalo
The State University of New York at Buffalo
School of Pharmacy and Pharmaceutical Sciences

Ancillary Course

June 20-22, 2013

Population PK/PD Modeling:
Introduction to NONMEM®

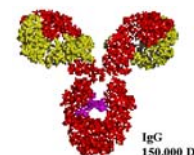
A "hands on"
computer tutorial.

Ancillary Course

June 20-21, 2013

Monoclonal Antibody
PK/PD

Dr. Joseph Balthasar
UB Center for
Protein Therapeutics



COURSE PROGRAM

June 13 Thursday
 08:00-08:30 Continental Breakfast/Registration
 08:30-09:45 W. Jusko: **Introductions: Pharmacokinetic Models & Perspectives**
 09:45-10:45 D. Mager: **Quantitative Structure-Pharmacokinetic Relationships**
 10:45-11:00 Break
 11:00-12:00 H-L. Fung: **Absorption & Biopharmaceutics**
 12:00-01:00 Lunch
 01:00-02:00 W. Jusko: **Absorption Kinetics**
 02:00-03:00 M. Morris: **Renal Clearance Concepts**
 03:00-03:15 Break
 03:15-04:15 M. Morris: **Hepatic Clearance Concepts**
 04:15-05:30 M. Morris: **Biliary Excretion & Enterohepatic Circulation**
 06:00-07:30 Dinner

June 14 Friday
 08:00-08:30 Continental Breakfast
 08:30-09:30 D. Mager: **Case Studies**
 09:30-10:30 W. Jusko: **Physiological Models I**
 10:30-10:45 Break

June 14 Friday, Cont'd.
 10:45-12:00 W. Jusko: **Physiological Models II**
 12:00-01:00 Lunch
 01:00-02:00 W. Jusko: **Physiological Models III**
 02:00-03:00 W. Jusko: **Physiological Models IV**
 03:00-03:15 Break
 03:15-04:15 D. Mager: **Protein & Antibody Kinetics**
 04:15-05:30 J. Balthasar: **Physiological Models of Proteins and Antibodies**

June 15 Saturday
 08:00-08:30 Continental Breakfast
 08:30-09:30 D. Mager: **Case Studies**
 09:30-10:30 D. Mager: **Metabolite Pharmacokinetics**
 10:30-10:45 Break
 10:45-12:00 W. Jusko: **Reversible Metabolism**
 12:00-01:00 Lunch
 01:00-02:00 D. Mager: **Target-Mediated PK**
 02:00-03:00 D. Mager: **Population Analysis**
 03:00-03:15 Break
 03:15-04:15 D. Mager: **Predicting Human PK**
 04:15-04:30 W. Jusko: **Summary**

REGISTRATION INFORMATION

Course location: The course will be held at The Conference Center Niagara Falls, 101 Old Falls Street, Niagara Falls, NY 14303. USA. Phone: (716) 278-2100. Fax: (716) 278-0008. The Conference Center is 28 min. from Buffalo International Airport. Website: <http://www.conferencecenterniagarafalls.com>

Hotel location: *Sheraton at the Falls*, 300 Third Street, Niagara Falls, NY 14303. USA. Phone: (716) 285-3361. The price is \$109/night. Hotel *Deadline: May 12, 2013.* Website: <http://sheratonatthefalls.com>

Fee: Individual fee: \$2400. This includes course documentation, mid-session refreshments, lunches and opening dinner. Up to 5 graduate students may enroll at a fee of \$1200. US Government rate: \$1800.

Registration: Please register ASAP in view of the limited course capacity of 40 participants. Confirmation of registration will be returned upon receipt, together with an invoice for the course fee. Registration will not be final until payment is received.

Cancellations: Cancellations with a full refund may be made until April 24, 2013. No refund is possible on cancellations received after this date. Substitutions may be made at any time.

Payment: University at Buffalo Foundation Inc. Bank transfers and credit card payments are accepted as well as checks. Course secretary: Rita Urben, (716) 645-4834.

Ancillary PK/PD Modeling Course: This course will be a separate 3-day course on Pharmacokinetic-Pharmacodynamic Modeling by UB Faculty. This course will use the facilities at The Conference Center Niagara Falls. The fee is \$2400 (Govt. \$1800, Students \$1200).

Ancillary Antibody PK/PD Workshop: This course will be a separate 2-day workshop on Monoclonal Antibody PK/PD by Dr. Joseph Balthasar. This course will utilize the facilities at The Conference Center Niagara Falls. The fee is \$1600 (Govt. \$1200, Students \$800).

Ancillary NONMEM® Course: A separate 3-day hands-on tutorial course in "Population PK Data Analysis using NONMEM®" will be provided by Prof. Jill Fiedler-Kelly and colleagues from Cognigen. Laptops with minimal configuration required. See separate flyer for details. The fee is \$2400. (Govt. \$1800, Students \$1200).

NOTE: *Those who wish to visit nearby Canada should bring a US Passport.*

REGISTRATION FORM: MECHANISTIC & PHYSIOLOGIC PHARMACOKINETICS

Name _____ Title _____ Organization _____
 Address: _____
 City: _____ State/Country: _____
 Postal Code: _____
 Telephone: _____ Fax: _____
 E-mail: _____
 Dinner, Thursday, June 13, 6:00 PM: _____ Will Attend _____ Will Not Attend _____ Vegetarian Meal Requested _____
 For credit card payment:
 Credit card number: _____
 Signature: _____ Expiration Date: _____

Kindly return to: MECHANISTIC & PHYSIOLOGIC PK, Dept. of Pharmaceutics, School of Pharmacy, University at Buffalo, 445 Kapoor Hall, Buffalo, NY 14214; phone: 716 645 4834; fax: 716 829 6569; e-mail Rita Urben at rrurben@buffalo.edu.