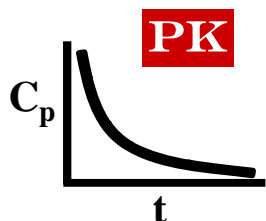


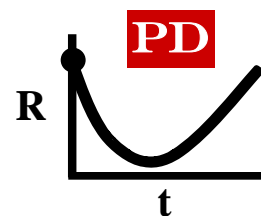
MAY 18-21, 2008: BUFFALO, NEW YORK

PHARMACOKINETIC-PHARMACODYNAMIC



MODELING

Concepts and Applications



COURSE OUTLINE

Significant progress has been made in the theory and applications of *pharmacodynamics*. On the basis of diverse *pharmacokinetic-pharmacodynamic modeling* concepts it is possible to describe and predict the time course of drug effects under various physiological and pathological conditions. The study of pharmacokinetic-pharmacodynamic relationships can be of considerable value in understanding drug action, summarizing extensive data, building a knowledge repository, finding optimal dosing regimens, and in making predictions under new circumstances.

This course will deal with the theoretical aspects and with the applications of PK/PD modeling. Subjects that will be presented include:

Basic pharmacodynamic theory: receptor binding, post-receptor events, and concentration-effect-time relationships.

Pharmacodynamic complexities: e.g. the role of distribution, metabolites, protein binding, animal scale-up; use of biomarkers and surrogate responses, models for pharmacogenomics.

Biophase compartment modeling: parametric and semi-parametric approaches.

Physiological pharmacodynamic modeling: indirect response models, cell lifespan models, chemotherapeutic effects.

Pharmacodynamic drug-drug interactions: isobolograms, competitive and non-competitive interactions.

Functional tolerance development: desensitization, counter-regulation, physiological feedback, indirect precursor models.

Population pharmacodynamics: application of NONMEM in pharmacodynamics, issues in use of covariates.

Specific drug applications: CNS active agents, cardiovascular agents, corticosteroids, anticoagulants, antibodies, antibiotics.

Special topics: Signal transduction, circadian rhythms, target-mediated PK/PD models, disease progression models.

Regulatory insights: use of pharmacometrics in drug approval and labeling.

"Thank you for the excellent PK/PD course. I really enjoyed the lectures and the 'Pearls of Wisdom'."

EGT May 2007

"The lectures were very educational, and fun too."

LZ May 2007

COURSE DIRECTION

William J. Jusko, PhD

Dr. Jusko is Distinguished Professor and Chair of Pharmaceutical Sciences at the School of Pharmacy and 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 drugs such as corticosteroids, tacrolimus and sirolimus and holds two NIH grants in the areas of corticosteroid PK/PD and mathematical modeling. He has authored over 480 publications, consults for the FDA, NIH, and the pharmaceutical industry, and is listed in ISI Most Highly Cited in Pharmacology.



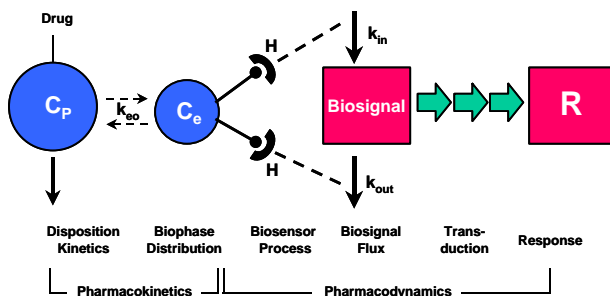
William J. Jusko, PhD

Ancillary Course A

May 15-17, 2008

Population PK/PD Modeling:
Introduction to NONMEM®

A "hands on"
computer tutorial.



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

Ancillary Course B

May 22-23, 2008

Use of PharSight Clinical
Trial Simulator

A "hands on"
computer tutorial.



COURSE PROGRAM

May 18	Sunday	6:30-7:00 Registration/Reception	10:00-11:00 Dr. W.J. Jusko: Modeling Irreversible Effects
		7:00-8:00 Dr. W.J. Jusko: History & Highlights	11:00-12:00 Dr. D. Mager: Modeling Transduction Processes
		8:00-9:30 Dinner	12:00-01:00 Lunch
May 19	Monday	08:00 Continental Breakfast	01:00-02:00 Dr. W.J. Jusko: Modeling Functional Adaptation
		08:30-08:45 Dr. W.J. Jusko: Introductions	02:00-03:00 Dr. D. Mager: Target-Mediated PK/PD Models
		08:45-09:45 Dr. D. Mager: Theory, Art, Practice of Modeling	03:00-03:15 Refreshments
		09:45-10:45 Dr. D. Mager: Basic Pharmacology & Simple Effects	03:15-04:15 Dr. W.J. Jusko: Modeling Drug Interactions
		10:45-11:00 Coffee	04:15-05:15 Dr. W.J. Jusko: Animal Scaling in PK/PD
		11:00-12:00 Dr. W.J. Jusko: Modeling Biophase Distribution	May 21
		12:00-01:00 Lunch	Wednesday
		01:00-02:00 Dr. W.J. Jusko: Basic Indirect Response Models	08:00 Continental Breakfast
		02:00-03:00 Dr. W. Krzyzanski: Cell Lifespan Models	08:30-09:45 Dr. W.J. Jusko: Review & Exercises II
		03:00-03:30 Break	09:45-10:00 Coffee
		03:30-04:30 Dr. W.J. Jusko: Complexities of Indirect Responses	10:00-11:00 Dr. J. Balthasar: Monoclonal Antibodies
May 20	Tuesday	08:00 Continental Breakfast	11:00-12:00 Dr. W.J. Jusko: Disease Progression Models
		08:30-09:45 Dr. D. Mager: Review & Exercises I	12:00-01:00 Lunch
		09:45-10:00 Coffee	01:00-02:00 Pf. J. Fiedler-Kelly: Population PK/PD Models
			02:00-03:00 Dr. J. Gobburu: FDA & Pharmacometrics
			03:00-03:15 Refreshments
			03:15-04:15 Dr. W.J. Jusko: Computational Issues in PK/PD
			04:15-05:15 Dr. W.J. Jusko: Final Discussion and Summary

REGISTRATION INFORMATION

Course location: The course will be held at the Ramada Inn & Conference Center, 2401 N. Forest Road, Amherst, New York 14226-0823, U.S.A. Phone: (716) 636-7500. Fax: (716) 636-8296. The Conference Center is 15 min. from Buffalo International Airport. The price is \$68/day. **Hotel Deadline: April 18, 2008.**

Fee: Individual fee: \$2200. This includes course documentation, mid-session refreshments, lunches and opening dinner during the course. Up to 5 graduate students may enroll at a fee of \$1100. US Government rate: \$1600.

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.

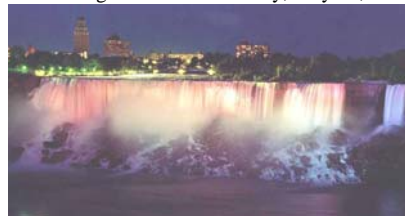
Cancellations: Cancellations with a full refund may be made until March 28, 2008. No refund is possible on cancellations received after this date. Substitutions may be made at any time.

Payment: University at Buffalo Foundation Inc. Bank transfers and credit card payments are accepted as well as checks. Course secretary: Rita Urben, (716) 645-2842 ext. 540.

Ancillary Clinical Trial Simulator Course: This course will be followed by an optional 2-day hands-on tutorial course in "Use of Clinical Trial Simulator" with primary instruction by Dr. Jeffrey Wald from GSK. This course will utilize the Computer Laboratory at The University at Buffalo. An additional fee of \$1500 is required (Govt. \$1200, Students \$750).

Ancillary NONMEM® Course: An optional 3-day hands-on tutorial course in "Population PK Data Analysis using NONMEM®" will be provided by Prof. Jill Fiedler-Kelly from Cognigen and Alan Forrest from UB. An additional fee of \$2200 is required (Govt. \$1600, Students \$1100).

Niagara Excursion: Cognigen Corporation will sponsor a bus trip to Niagara Casino and Niagara Falls on Monday, May 19, at 5:30 PM.



REGISTRATION FORM: Pharmacokinetic-Pharmacodynamic Modeling, May 18-21, 2008.

**NONMEM®, May 15-17, 2008.
Clinical Trial Simulator, May 22-23, 2008.**

Name _____ Title _____ Organization _____
 Address _____
 City _____ State/Country _____ Postal Code _____
 Telephone _____ Fax _____ Email _____

Opening Reception/Dinner, Sunday, May 18, 6:30 PM: _____ Will Attend _____ Will Not Attend Vegetarian Meal Requested _____
 Excursion to Niagara Falls, Monday, May 19, 5:30 PM: _____ Will Attend _____ Will Not Attend _____
 Population PK (NONMEM®) Course: _____ Will Attend _____ Will Not Attend _____
 Clinical Trial Simulator Course: _____ Will Attend _____ Will Not Attend _____

Signature _____ Date _____

Please return to: PK/PD MODELING, Department of Pharmaceutical Sciences, School of Pharmacy, State University of New York at Buffalo, 519 Hochstetter Hall, Buffalo, NY 14260; phone: (716) 645-2842, ext. 225; fax: (716) 645-3693; Email: wjjusko@buffalo.edu