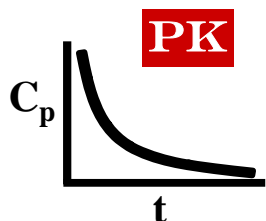


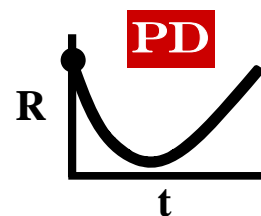
MAY 16-19, 2010: BUFFALO, NEW YORK

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 (by an FDA scientist).

"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, antidiabetic drugs, and holds two NIH grants in the areas of corticosteroid PK/PD and mathematical modeling. He has authored over 520 publications, consults for the FDA, NIH, and the pharmaceutical industry, and is listed in ISI Most Highly Cited in Pharmacology.



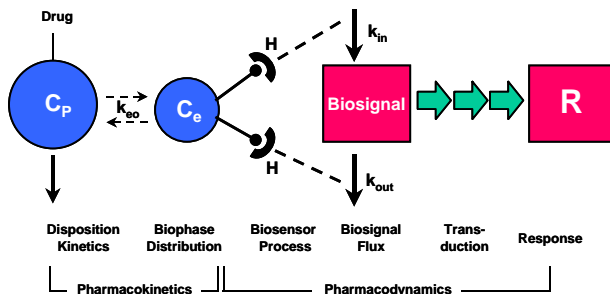
William J. Jusko, PhD

Ancillary Course A

May 13-15, 2010

Population PK/PD Modeling:
Introduction to NONMEM®

A "hands on"
computer tutorial.



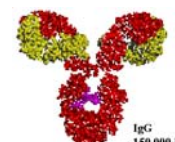
UB University at Buffalo
The State University of New York at Buffalo
School of Pharmacy and Pharmaceutical Sciences

Ancillary Course B

May 20-21, 2010

Monoclonal Antibody
PK/PD

Dr. Joseph Balthasar



IgG
150,000 Da

COURSE PROGRAM

<p>May 16 Sunday 6:30-7:00 Registration/Reception 7:00-8:00 Dr. W.J. Jusko: History & Highlights 8:00-9:30 Dinner</p>	<p>May 17 Monday 08:00 Continental Breakfast 08:30-08:45 Dr. W.J. Jusko: Introductions 08:45-09:45 Dr. D. Mager: Theory, Art, Practice of Modeling 09:45-10:45 Dr. D. Mager: Basic Pharmacology & Simple Effects 10:45-11:00 Coffee 11:00-12:00 Dr. W.J. Jusko: Modeling Biophase Distribution 12:00-01:00 Lunch 01:00-02:00 Dr. W.J. Jusko: Basic Indirect Response Models 02:00-03:00 Dr. W. Krzyzanski: Cell Lifespan Models 03:00-03:30 Break 03:30-04:30 Dr. W.J. Jusko: Complexities of Indirect Responses</p>	<p>10:00-11:00 Dr. W.J. Jusko: Modeling Irreversible Effects 11:00-12:00 Dr. D. Mager: Modeling Transduction Processes 12:00-01:00 Lunch 01:00-02:00 Dr. W.J. Jusko: Modeling Functional Adaptation 02:00-03:00 Dr. D. Mager: Target-Mediated PK/PD Models 03:00-03:15 Refreshments 03:15-04:15 Dr. W.J. Jusko : Modeling Drug Interactions 04:15-05:15 Dr. W.J. Jusko: Animal Scaling in PK/PD</p>	<p>May 19 Wednesday 08:00 Continental Breakfast 08:30-09:45 Dr. W.J. Jusko: Review & Exercises II 09:45-10:00 Coffee 10:00-11:00 Dr. D. Mager: Monoclonal Antibodies 11:00-12:00 Dr. W.J. Jusko: Disease Progression Models 12:00-01:00 Lunch 01:00-02:00 Pf. J. Fiedler-Kelly: Population PK/PD Models 02:00-03:00 Dr. C. Tornoe: 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</p>
<p>May 18 Tuesday 08:00 Continental Breakfast 08:30-09:45 Dr. D. Mager: Review & Exercises I 09:45-10:00 Coffee</p>			

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 \$69/day. **Hotel Deadline: April 16, 2010.**

Fee: Individual fee: \$2400. 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 \$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 March 26, 2010. 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 Antibody PK/PD Workshop: This course will be an optional 2-day workshop on Monoclonal Antibody PK/PD by Dr. Joseph Balthasar. This course will utilize the facilities at the Ramada Inn. An additional fee of \$1600 is required (Govt. \$1200, Students \$800).

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 Forrester 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 17, at 5:30 PM.



REGISTRATION FORM: Pharmacokinetic-Pharmacodynamic Modeling, May 16-19, 2010.

**NONMEM®, May 13-15, 2010.
Antibody PK/PD, May 20-21, 2010.**

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

Opening Reception/Dinner, Sunday, May 16, 6:30 PM: _____ Will Attend _____ Will Not Attend Vegetarian Meal Requested _____
 Excursion to Niagara Falls, Monday, May 17, 5:30 PM: _____ Will Attend _____ Will Not Attend
 Population PK (NONMEM®) Course: _____ Will Attend _____ Will Not Attend
 Antibody PK/PD Workshop: _____ 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) 645-4834; fax: (716) 645-3693; Email: rruurben@buffalo.edu