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).
### Course Program

**May 22**
- **Sunday**
  - 6:30-7:00 Registration/Reception
  - 7:00-8:00 Dr. W.J. Jusko: *History & Highlights*
  - 8:00-9:30 Dinner

**May 23**
- **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*

**May 24**
- **Tuesday**
  - 08:00 Continental Breakfast
  - 08:30-09:45 Dr. W.J. Jusko: *Modeling Biophase Distribution*
  - 11:00-12:00 Dr. W.J. Jusko: *Modeling Biophase Distribution*
  - 12:00-13:00 Lunch

**May 25**
- **Wednesday**
  - 08:00 Continental Breakfast
  - 08:30-08:45 Dr. W.J. Jusko: *Review & Exercises II*

### 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 $70/day. *Hotel Deadline: April 18, 2011.*

**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, 2011. 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 a separate 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:** 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. An additional fee of $2200 is required (Govt. $1600, Students $1100).

**Niagara Falls Excursion:** Cognigen Corporation will sponsor a bus trip to Niagara Falls on Monday, May 23, at 5:30 PM. Dinner and sightseeing at the Falls will be included.


**Name**  
**Address**  
**City**  
**State/Country**  
**Postal Code**  
**Telephone**  
**Fax**  
**Email**

**Opening Reception/Dinner, Sunday, May 22, 6:30 PM:**  
- Will Attend  
- Will Not Attend  
- Vegetarian Meal Requested

**Excursion to Niagara Falls, Monday, May 23, 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

**For credit card payment:** Please circle:  
- Visa  
- Mastercard  
- American Express  
- Discover

**Credit card number:**  
**Expiration 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: rrurben@buffalo.edu