

# PHARMACOKINETIC-PHARMACODYNAMIC MODELING

## Concepts and Applications

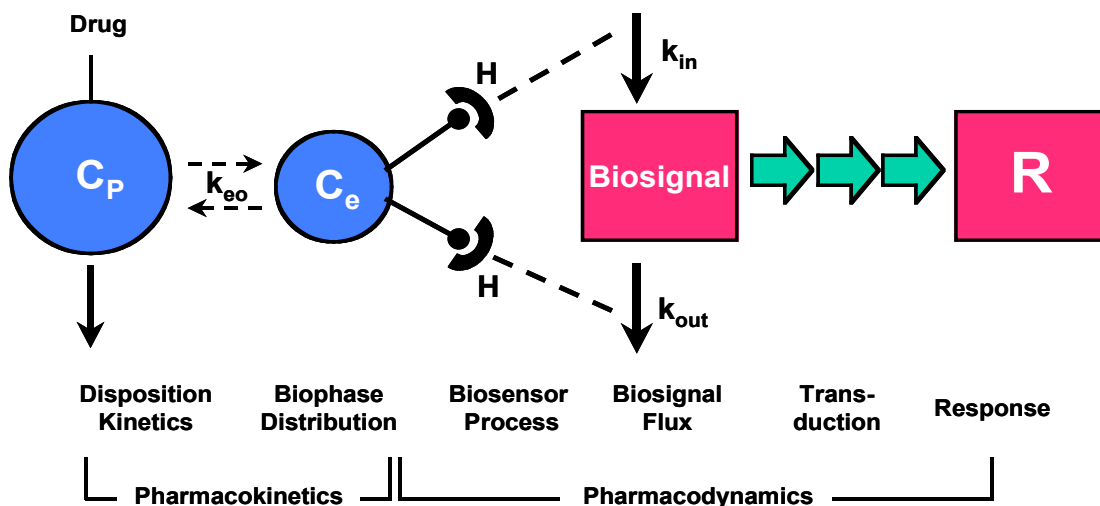
January 7-8-9, 2009

PROFESSOR OF  
PHARMACEUTICAL  
SCIENCES

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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.

## 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.

**Pharmacokinetics of peptides and proteins**

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

**Protein pharmacodynamics:** application of pharmacodynamics to diverse proteins.

**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.

# COURSE PROGRAM

## January 7 Wednesday

- 08:00 Continental Breakfast  
08:30 J.-M. Scherrmann: Introductions  
08:45 W. Jusko: History & Highlights of PK/PD Modeling  
09:45 D. Mager: Theory, Art, & Practice of PK/PD Modeling  
10:45 Coffee  
11:00 J. Balthasar: Antibody Pharmacokinetics  
12:00 Lunch  
13:00 D. Mager: Basic Pharmacology & Simple Direct Effects  
14:00 W. Jusko: Biophase Models  
15:00 Break  
15:15 W. Jusko: Basic Indirect Response Models  
16:15 J. Balthasar: Antibody Pharmacodynamics

## January 8 Thursday

- 08:00 Continental Breakfast  
08:30 J. Balthasar: Bimolecular Interactions in Dynamics  
09:45 Coffee  
10:00 W. Jusko: Extended Indirect Response Models  
11:00 D. Mager: Transduction Models  
12:00 Lunch  
13:00 W. Jusko: Chemotherapy Models  
14:00 D. Mager: Basic Target-Mediated PK/PD Models  
15:00 Break  
15:15 J. Balthasar: TMDD Applied to Monoclonal Antibodies  
16:15 W. Jusko: Animal Scaling in PK/PD

## January 9 Friday

- 08:00 Continental Breakfast  
08:30 All: Review & Exercises  
09:45 Coffee  
10:00 D. Mager: Functional Adaptation Models  
11:00 W. Jusko: Disease Progression Models  
12:00 Lunch  
13:00 J. Balthasar: PBPK Models for Monoclonal Antibodies  
14:00 D. Mager: Population PK/PD Models  
15:00 Break  
15:15 J. Balthasar: Development of New Immunotherapies  
16:15 W. Jusko: Computational Issues in PK/PD



Dr. Mager is an Assistant Professor of Pharmaceutical Sciences at the University at Buffalo, State University of New York. 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 American Association of Pharmaceutical Scientists in 2007. Dr. Mager has served as a Visiting Professor at the Université René Descartes – Paris V. Dr. Mager has also served 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-platelet, anti-cancer, and immunomodulatory pharmacotherapy.



*Dr. Balthasar is Professor of Pharmaceutical Sciences at the University at Buffalo, State University of New York and Director of the Center for Protein Therapeutics. His PK/PD modeling interests and capabilities include the development and preclinical evaluation of anti-toxin immunotherapy, the development and preclinical evaluation of anti-cancer immunotherapies (including immunoconjugate immunotherapies), and the development and preclinical evaluation of novel immunotherapies for humoral autoimmune conditions (immune thrombocytopenia, myasthenia gravis). He serves as a consultant to the NIH and pharmaceutical industry.*

## REGISTRATION INFORMATION

FEES : 2100 euros (meals included) for all registrations before december, 1st  
2400 euros (meals included) after this date

Payement : by chek only for french public) to l'Agent Comptable de l'université Paris Descartes  
Or by bank transfer only

### IDENTIFIANT NATIONAL DE COMPTE BANCAIRE (RIB)

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## REGISTRATION FORM : January 7-8-9, 2009. Pharmacokinetic-Pharmacodynamic Modeling,

### COMPANY DETAILS

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### PERSONNAL DETAILS

Title  Mr  Mrs

FIRST NAME \_\_\_\_\_ LAST NAME \_\_\_\_\_

Jobtitle \_\_\_\_\_

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Date, Signature

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