2-DAY WORKSHOP ON MONOCLONAL ANTIBODY PHARMACOKINETICS & PHARMACODYNAMICS
Concepts and Applications

This workshop has been designed to provide a detailed discussion of issues relevant to the pharmacokinetic / pharmacodynamic (PK/PD) modeling of antibody drugs. Lectures will address primary determinants of antibody pharmacokinetics (PK) and pharmacodynamics (PD), the design and implementation of pre-clinical investigations of antibody PK/PD, and state-of-the-art mathematical models to characterize and predict antibody PK and PD. Special emphasis is placed on discussion of the role of FcRn on the absorption, distribution, and elimination of antibodies, on the mathematical modeling of target-mediated antibody disposition, and on physiologically-based modeling of antibody pharmacokinetics. The workshop content is provided as a combination of formal lectures and informal review sessions.

Subjects that will be presented include:

**Determinants of antibody pharmacokinetics and pharmacodynamics:** mechanisms of antibody elimination, the role of convection in the kinetics of antibody distribution, the role of FcRn in antibody absorption, distribution, and elimination

**Common analytical assays for quantification of antibody in biological samples & implications for PK/PD investigations**

**Immunogenicity and Antibody PK/PD**

**Evaluation of biosimilarity of antibody drugs:** Application of PK/PD for biosimilarity studies – opportunities and limitations

**Interspecies Scaling of Antibody PK**

**Target-Mediated Antibody Disposition:** modeling, implications for interspecies scaling, implications for First-in-Human studies

**Modeling of bimolecular antibody-ligand interaction**

**Physiologically-based pharmacokinetic modeling:** Incorporation of FcRn-mediated antibody transport in PBPK models, incorporation of target-mediated disposition, use of PBPK and preclinical data to predict antibody disposition in humans

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**COURSE DIRECTION**

**Joseph P. Balthasar, PhD**

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 immunotherapies, 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.
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

Fee: $1600. A US government employee rate of $1200 and additional 5% off is available for those with an active government I.D. The fee includes 3 days of course content, snacks, lunches, and break-time refreshments during the course are included.

REGISTRATION DETAILS

Hotel: Sheraton at the Falls, 300 Third Street, Niagara Falls, NY 14303. Phone: (716) 285-3361. The price is $109/night. Hotel deadline: April 9, 2012. Website: http://sheratonatthefalls.com

Registration: Given the special nature of the course, enrollment will be limited to 30 persons. Please register by filling out the form and returning to the address shown below. 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. Checks should be made out to the University at Buffalo Foundation Inc. Bank transfers and credit card payments are also accepted.

REGISTRATION FORM: ANTIBODY WORKSHOP

Name: __________________________________________
Organization: __________________________________
Address: _________________________________________
City: __________________________ State/Country: __________
Postal Code: __________________________
Telephone: __________________ Fax: __________ E-mail: __________
For credit card payment: ________________________
Credit card number: ____________________________
Signature: ________________________________ Expiration Date: __________________

Kindly return to: ANTIBODY PK/PD MODELING Workshop, Dept. of Pharmaceutics, School of Pharmacy, University at Buffalo, 519 Hochstetter Hall, Buffalo, NY 14260; phone: 716 645-4834; fax: 716 645 3693; e-mail Rita Urban at rrurban@buffalo.edu.

AGENDA

Day 1
08:45-09:00  Introduction
09:00-10:45  Introduction to Antibody Pharmacokinetics
10:45-11:00 Break
10:45-11:15  Analytical Assays for Antibodies: Implications for PK/PD Analyses
11:15-12:00 Interspecies Scaling of Antibody PK & PD
12:00-12:45 Lunch
12:45-01:15 Use of PK/PD Studies to Support Comparability: Assessments of Therapeutic Proteins: An Academic Perspective
01:15-01:45 Immunogenicity and Macromolecule PK/PD
01:45-02:15 Biologies and Drug-Drug Interactions
02:15-03:00 Mathematical Modeling of Target-Mediated Disposition of Monoclonal Antibodies
03:00-03:15 Break
03:15-03:30 Review Module #1:  Design & Analysis of a Preclinical Investigation of Antibody PK
03:30-03:45 Mathematical Modeling of Bimolecular Antibody-Antigen Interaction
03:45-05:00 Review Module #2:  Design & Analysis of a Preclinical Investigation of Antibody PK (Part 2)
05:00-05:15 Break
05:15-06:30 Review Module #3:  Prediction of the Influence of Shed Antigen on the Distribution of Mab in Solid Tumors
06:30-07:00 Review Module #4

Day 2
09:00-10:00 Mathematical Modeling of Bimolecular Antibody-Antigen Interaction
10:00-11:00 Review Module #2:  Design & Analysis of a Preclinical Investigation of Antibody PK (Part 2)
11:00-11:15 Mathematical Modeling of Bimolecular Antibody-Antigen Interaction
11:15-12:15 Review Module #3:  Prediction of the Influence of Shed Antigen on the Distribution of Mab in Solid Tumors
12:15-01:00 Lunch
12:30-01:00 Review Module #4
01:00-02:00 Review Module #3
02:00-03:00 Review Module #2
03:00-03:15 Break
03:15-03:30 Review Module #1
03:30-03:45 Review Module #2
03:45-05:00 Review Module #3