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.
AGENDA

Day 1
08:45-09:00  Introductions
09:00-10:45  Introduction to Antibody Pharmacokinetics
    • Introduction to antibodies (isotypes, polyclonal vs. monoclonal, humanization, etc.)
    • Mechanistic determinants of antibody absorption, distribution, and elimination (contrasting with determinants of small-molecule ADME)
    • Comments on the mathematical modeling of antibody PK
    • Recent research relating to the role of FcR and mAb PK
  Break
10:45-11:00  Use of PK/PD Studies to Support Comparability
10:45-11:15  Mathematical Modeling of Monoclonal Antibodies

Day 2
09:00-10:00  Mathematical Modeling of Bimolecular Antibody-Antigen Interaction
    • Review of preclinical investigation of antibody PK
    • Study objectives
    • Consideration for study design
    • Assay considerations
    • Initial characterization of ADME (NCA vs. modeling)
    • Evaluation of NCA results
  Break
10:00-11:00  Physiologically-Based PK Modeling of Mab
    • Review of PBPK models
    • Application of PBPK models applied to Mab
    • Discussion of major features of PBPK models for Mab & review of the mathematical modeling of antibody PK

REGISTRATION DETAILS

Course location: The course will be held at the University at Buffalo, North Campus.

Fee: The fee is $1600. A US government employee rate of $1200 and student rate of $800 is available for up to 3 participants of each type. The registration fee includes course documentation and handouts. Lunches and break-time refreshments during the course are included.

Accommodations: Ramada Inn & Conference Center, 716-636-7500 or Marriott Hotel, 716-689-6900.

REGISTRATION FORM: ANTIBODY WORKSHOP

Name: _____________________________________________________
Organization: ______________________________________________
Address: ___________________________________________________
City: __________________________________ State/Country: __________
Postal Code: __________________________ Fax: _______________ E-mail: __________________________
Telephone: __________________________

For credit card payment:
Credit card number: __________________________
Expiration Date: __________________________

Signature: __________________________

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 rruben@buffalo.edu.