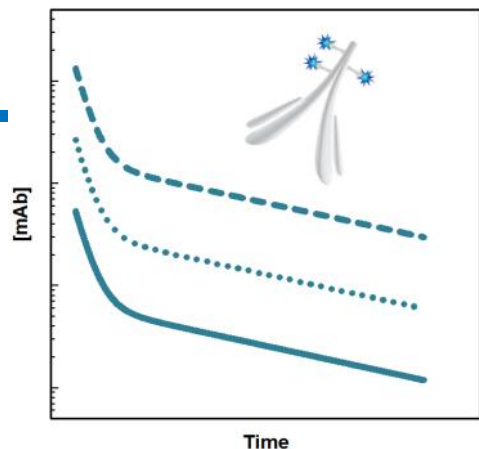


2nd BioTx ADME WORKSHOP Cosponsored with AAPS



Topics Include:

- ◆ ADME principles and technologies
- ◆ Extra-vascular delivery and absorption
- ◆ Analytical tools for biotherapeutics
- ◆ Bioconjugates
- ◆ Current and evolving trends in utilization of ADME data in industry

Registration and poster abstract submission now open. Space is limited!



ADME of Protein Therapeutics: *Science and Application*

August 11-12, 2013 | Buffalo, NY

Workshop Goals

- ◆ To provide an overview of ADME (Absorption, Distribution, Metabolism/Catabolism, Excretion) principles and technologies for protein therapeutics.
- ◆ To discuss the utility of mechanistic studies of protein therapeutics for lead optimization and human translation.
- ◆ To provide an overview of strategies and challenges in understanding and optimizing ADME properties of bioconjugate protein modalities.
- ◆ To discuss current knowledge in the extravascular delivery of protein therapeutics.

Presenters & Organizers:

- ◆ NIH
- ◆ University at Buffalo
- ◆ Rutgers University
- ◆ UCB
- ◆ Roche
- ◆ Genentech
- ◆ Pfizer
- ◆ Amgen
- ◆ Seattle Genetics
- ◆ Merck
- ◆ Janssen

Preliminary Program

Registration 2:00-2:45

Sunday Session I

Introductory session (Dr. J. Tibbitts, Chair)

- 2:50 Welcome and opening remarks (Dr. J. Balthasar, UB, and Dr. Y. Vugmeyster, Pfizer)
- 3:00 Characteristics of therapeutic proteins (Dr. J. Tibbitts, UCB)
- 3:15 Absorption (Dr. W. Richter, Roche)
- 3:45 Distribution (Dr. A. Boswell, Genentech)
- 4:15 Catabolism/Elimination (Dr. J. Balthasar, UB)
- 4:45 BREAK

Sunday Session II

Case studies on extra-vascular delivery and absorption (Dr. L. Kagan, Chair)

- 5:00 Pharmacokinetic modeling of subcutaneous absorption (Dr. L. Kagan, Rutgers)
- 5:30 Skin metabolism of biotherapeutics as a limiting factor for SC bioavailability (Dr. M. Wang, Pfizer)
- 6:00 Practical considerations on pulmonary delivery of biologics (Dr. X. Xu, NIH)

Monday Session I

Analytical tools for biotherapeutics (Dr. D. O'Hara, Chair)

- 8:30 Quantitative measurements of protein therapeutics using radiolabeled methods and ligand binding assays (Dr. D. O'Hara, Pfizer)
- 9:00 Use of LC-MS to measure Biotherapeutics in biological samples (TBD)
- 9:30 Biotransformation and in vivo stability of novel protein therapeutics: impact on candidate selection and pharmacokinetic profiling (Dr. M. Hall, Amgen)
- 10:00 BREAK

Monday Session II

Bioconjugates (Dr. T. Han and Dr. L. Khawli, Chairs)

- 10:15 Introduction (Dr. T. Han, Seattle Genetics)
- 10:20 Exploring the Metabolism and Disposition of Antibody Drug Conjugates (ADCs): Case Studies (Dr. K. Lin, Genentech)
- 11:00 Characterizing ADC Efficacy and Toxicity: the bioanalytical challenges (Dr. D. Rock, Amgen)
- 11:30 ADME of pegylated-protein conjugates (Dr. T. Parton, UCB)
- 12:00 Panel discussion (Dr. L. Khawli, Genentech, Dr. T. Han, Seattle Genetics)

Lunch and Poster Session 12:30-2:30

Monday Session III

Current and evolving trends in utilization of ADME data in the industry: PKPD modeling, lead optimization, and human translation (Dr. J. Balthasar and Dr. T. Prueksaritanont, Chairs)

- 2:30 ADME properties of therapeutic peptides: Lessons learned and strategies for lead optimization (Dr. V. Reddy, Merck)
- 3:00 Distribution of mAbs and its ability to neutralize targets at the site of action (TBD)
- 3:30 Atypical antibody pharmacokinetics and human translation (D. Bumbaca, Genentech)
- 4:00 BREAK
- 4:15 Physiologically-based models for predicting mAb pharmacokinetics (Dr. J. Balthasar, UB)
- 4:45 Agonistic TAM-163 antibody targeting tyrosine kinase receptor-B: Applying mechanistic modeling to enable preclinical to clinical translation and guide clinical trial design (Dr. Y. Vugmeyster, Pfizer)
- 5:15 Additional questions
- Closing remarks (Dr. J. Balthasar, UB, and Dr. Y. Vugmeyster, Pfizer)

Picnic 6:00-8:00

Registration Information

Registration: Please register by filling out the registration form and returning to the address shown below. Confirmation of registration will be returned upon receipt.

Poster Presentation: Send poster abstract submissions (350 word limit) to frankeng@buffalo.edu

Fee: Industry participants \$100. Fee is waived for registrants from academia, however registration must be submitted.

Payment Information: University at Buffalo Foundation Inc. Bank transfers, credit card payments and checks are accepted.

Return to: ADME BioTx Workshop, Dept. of Pharmaceutical Sciences, University at Buffalo, 445 Kapoor Hall, Buffalo, NY, 14214; phone: (716) 645-4834, fax: (716) 645-3693; email Rita Urben at rrurben@buffalo.edu

Workshop Location: University at Buffalo, North Campus, 121 Cooke hall. Lunches and break-time refreshments will be provided.

Accommodations: Ramada Inn (716) 636-7500, Marriott Hotel (716) 689-6900, or DoubleTree (716) 689-4414.

Registration Form

Name: _____

Organization: _____

Address: _____

City: _____ State/Country: _____

Postal Code: _____ Telephone: _____

Fax: _____ E-mail: _____

Credit card payment: Please circle:

Visa
 Mastercard
 American Express
 Discover

Credit card number: _____

Expiration Date: _____

Signature: _____

**Registration and Poster Abstract Submission
Deadline: July 29th, 2013**