

## Pharmacokinetics and Pharmacodynamics of Protein Therapeutics: Concepts and Hands-On Modeling and Simulation

University of Tennessee Health Science Center, Memphis , TN, USA, April 1-5, 2019

Course Directors: Bernd Meibohm, University of Tennessee, and Johan Gabrielsson, Swedish University of Agricultural Sciences SLU

- Tentative Schedule -

Time	Monday, Apr 1	Tuesday, Apr 2	Wednesday, Apr 3	Thursday, Apr 4	Friday, Apr 5
Topic	Basic Concepts	Drug Disposition	PK/PD	Developmental Aspects	Immunogenicity
8:30-9:15	Introduction & Structure of Protein Therapeutics (Bernd Meibohm)	Basic Concepts of Target-Mediated Drug Disposition II (Johan Gabrielsson)	Projection of Human PK of Monoclonal Antibodies (Doug Leipold)	Early Development of Protein Therapeutics: PKPD Strategies (Doug Leipold)	Bioanalysis: Principles of Biological Analyte Quantification (Gopi Shankar)
9:20-10:05	Basic PK of Peptides & Proteins I (Bernd Meibohm)	Drug Disposition of Monoclonal Antibodies (Bernd Meibohm)	PKPD Modeling & Simulation: Concepts of turnover models (Johan Gabrielsson)	Model-Based Decision Support in Discovery (Stacey Tannenbaum)	Immunogenicity: Impact on PK and PD (Bernd Meibohm)
	<i>Break</i>	<i>Break</i>	<i>Break</i>	<i>Break</i>	<i>Break</i>
10:25-11:10	Basic PK of Peptides & Proteins II (Comparison w/ small molecules) (Bernd Meibohm)	Tissue and Tumor Penetration (Bernd Meibohm)	PKPD Modeling & Simulation: Complex turnover models (Johan Gabrielsson)	Design, delivery, and development of bispecific antibody formats (Sid Sukumaran)	Challenges in Immunogenicity Bioanalysis (Gopi Shankar)
11:15-12:00	Basic Concepts of Target-Mediated Drug Disposition I (Johan Gabrielsson)	PKPD Modeling & Simulation: Concepts of Rapid Equil and Distrib (Bernd Meibohm)	Clinical Pharmacology M&S Strategies for Antibody Drug Conjugates (Vijay Upreti)	Clinical Pharmacology Challenges for Protein Therapeutics (Bernd Meibohm)	Clinical Immunogenicity & Reporting (Gopi Shankar)
	<i>Lunch</i>	<i>Lunch</i>	<i>Lunch</i>	<i>Lunch</i>	<i>Lunch</i>
1:00-1:45	Hands-on Maxsim2 Lab I (Johan Gabrielsson )	Hands-on Maxsim2 Lab III (Johan Gabrielsson & Bernd Meibohm)	Strategies for First in Human Dose Selection of Protein Therapeutics (Vijay Upreti)	Disease States and Covariates Modulating the PKPD of Protein Therapeutics (Bernd Meibohm)	Wrap-up (Bernd Meibohm)
1:55-2:40	Hands-on Maxsim2 Lab I (Johan Gabrielsson)	Hands-on Maxsim2 Lab III (Johan Gabrielsson & Bernd Meibohm)	Nonclinical & Clinical Pharmacology Considerations for Designing FIH Trials (Sid Sukumaran)	Evaluation of Drug-Drug Interaction for Protein Therapeutics (Bernd Meibohm)	
	<i>Break</i>	<i>Break</i>	<i>Break</i>	<i>Break</i>	
3:00-3:55	Hands-on Maxsim2 Lab II (Johan Gabrielsson)	Pattern Recognition Exercises (Johan Gabrielsson and Bernd Meibohm)	Group Exercises: PKPD Modeling (Johan Gabrielsson and Bernd Meibohm)	Model-Based Decision Support in Development (Stacey Tannenbaum)	
4:05-5:00	Wrap-up of Maxsim2 Lab II (Johan Gabrielsson)	Pattern Recognition Exercises (Johan Gabrielsson and Bernd Meibohm)	Group Exercises: PKPD Modeling (Johan Gabrielsson and Bernd Meibohm)	Biosimilar Development - A Nightmare or a Piece of Cake? (Bernd Meibohm)	