

2021 Pharmacokinetics and Pharmacodynamics of Protein Therapeutics: Concepts and Hands-On Exercises

April 12-16, 2021

Course Directors: Bernd Meibohm, University of Tennessee, and Johan Gabrielsson, Biopharmacon, Gothenburg

- Course Schedule (in US Central Standard Time) -

Time	Monday, April 12	Time	Tuesday, April 13	Time	Wednesday, April 14	Time	Thursday, April 15	Time	Friday, April 16
Topic	Basic Concepts	Topic	Drug Disposition	Topic	PK/PD	Topic	Developmental Aspects	Topic	Immunogenicity
9:00	Introduction (Bernd Meibohm & Johan Gabrielsson)	9:00	Discussion of MaxSim2 Homework (Johan Gabrielsson & Bernd Meibohm)	9:00	Discussion of TMDD Steady State Exercise (Johan Gabrielsson & Bernd Meibohm)	9:00	Discussion of Practical Biologics Homework (Johan Gabrielsson & Bernd Meibohm)	9:00	Discussion of Clinical Pharmacology Homework (Johan Gabrielsson & Bernd Meibohm)
9:15	Basic Pharmacokinetics of Proteins (Bernd Meibohm)	9:30	TMDD: Steady-state relationship of ligand, target and complex I (Johan Gabrielsson)	9:30	Extravascular Administration of Proteins (Bernd Meibohm)	9:30	Early Development of Protein Therapeutics: PKPD Strategies (Doug Leipold)	9:30	PKPD of Proteins in Pediatrics (Bernd Meibohm)
9:45	<i>Discussion</i>	10:00	<i>Discussion</i>	10:00	<i>Discussion</i>	10:00	<i>Discussion</i>	10:00	<i>Discussion</i>
10:00	Drug Disposition of Monoclonal Antibodies (Bernd Meibohm)	10:15	TMDD: Steady-state relationship of ligand, target and complex II (Johan Gabrielsson)	10:15	Projection of Human PK of Monoclonal Antibodies (Raj Yadav)	10:15	Nonclinical & Clinical Pharmacology Considerations for Designing FIH Trials (Sid Sukumaran)	10:15	Model-Based Decision Support in Development (Stacey Tannenbaum)
10:30	<i>Discussion</i>	10:45	<i>Discussion</i>	10:45	<i>Discussion</i>	10:45	<i>Discussion</i>	10:45	<i>Discussion</i>
10:45	Break	11:00	Break	11:00	Break	11:00	Break	11:00	Break
11:00	Basic Concepts of Target-Mediated Drug Disposition I (Johan Gabrielsson)	11:15	PKPD Modeling and Simulation: Concepts of Rapid Equilibrium (Bernd Meibohm)	11:15	Strategies for First in Human Dose Selection of Protein Therapeutics (Vijay Upreti)	11:15	Clinical Pharmacology Challenges for Protein Therapeutics (Bernd Meibohm)	11:15	Immunogenicity: Impact on PK and PD (Bernd Meibohm)
11:30	<i>Discussion</i>	11:45	<i>Discussion</i>	11:45	<i>Discussion</i>	11:45	<i>Discussion</i>	11:45	<i>Discussion</i>
11:45	Basic Concepts of Target-Mediated Drug Disposition II (Johan Gabrielsson)	12:00	PKPD Modeling and Simulation: Concepts of Turnover Models (Johan Gabrielsson)	12:00	Clinical Pharmacology Strategies for Antibody Drug Conjugates and Bispecific T-cell Engagers (Vijay Upreti)	12:00	Disease States & Covariates Modulating PKPD of Proteins (Bernd Meibohm)	12:00	Challenges in Immunogenicity Bioanalysis (Gopi Shankar)
12:15	<i>Discussion</i>	12:30	<i>Discussion</i>	12:30	<i>Discussion</i>	12:30	<i>Discussion</i>	12:30	<i>Discussion</i>
12:30	Break	12:40	Cytokinetic Models (Bernd Meibohm)	12:45	Break	12:45	Break	12:45	Break
12:45	MaxSim2 Demonstration & Homework (Johan Gabrielsson & Bernd Meibohm)	12:50	Break	13:00	Pattern Recognition Exercises PK (Johan Gabrielsson & Bernd Meibohm)	13:00	Design, Delivery, and Development of Bispecific Antibody Formats (Sid Sukumaran)	13:00	Clinical Immunogenicity & Reporting (Gopi Shankar)
13:15	<i>Discussion</i>	13:00	Pattern Recognition Exercises PD (Johan Gabrielsson & Bernd Meibohm)	13:00	Pattern Recognition Exercises PD (Johan Gabrielsson & Bernd Meibohm)	13:00	Design, Delivery, and Development of Bispecific Antibody Formats (Sid Sukumaran)	13:00	Clinical Immunogenicity & Reporting (Gopi Shankar)
13:30	MaxSim2 Demonstration & Homework (Johan Gabrielsson & Bernd Meibohm)	13:30	<i>Discussion</i>	13:30	<i>Discussion</i>	13:30	<i>Discussion</i>	13:30	<i>Discussion</i>
13:30	MaxSim2 Demonstration & Homework (Johan Gabrielsson & Bernd Meibohm)	13:45	TMDD Steady State Exercise (Johan Gabrielsson & Bernd Meibohm)	13:45	Practical Biologics Homework (Johan Gabrielsson & Bernd Meibohm)	13:45	Clinical Pharmacology Homework (Johan Gabrielsson & Bernd Meibohm)	13:45	Wrap up (Johan Gabrielsson & Bernd Meibohm)
14:00	End Day 1	14:00	End Day 2	14:00	End Day 3	14:00	End Day 4	14:00	End Day 5