

Advances in PBPK Modeling and its Regulatory Utility for Oral Drug Product Development

Session 2: PBPK Modeling to Evaluate Food Impact on Bioequivalence Supporting ICH M13A

<i>Presenters:</i>	Rodrigo Cristofolletti, PhD	Assistant Professor, University of Florida
	Jozef Al-Gousous, PhD	Lecturer, Johannes Gutenberg University Mainz
	Peter Langguth, RPh, PhD	Lecturer, Johannes Gutenberg University Mainz
	Rebeka Jereb, PhD	Senior Scientist Clinical Innovations, Lek, a Sandoz company
<i>Moderator:</i>	Ethan Stier, PhD, RPh	Associate Director for Lifecycle Management, OCP, OTS, FDA
	Tycho Heimbach, PhD, FAAPS	Merck & Co.
<i>Panelists:</i>	Tausif Ahmed, PhD	VP & Head, Biopharmaceutics & Bioequivalence, Dr. Reddy's Laboratories Ltd
	Jozef Al-Gousous, PhD	Lecturer, Johannes Gutenberg University Mainz
	Susana Almeida, PhD	Clinical Development and Safety Officer, Medicines for Europe
	Rodrigo Cristofolletti, PhD	Assistant Professor, University of Florida
	Jianghong Fan, PhD	Senior Staff Fellow, DPM, OCP, OTS, CDER, FDA
	Rebeka Jereb, PhD	Senior Scientist Clinical Innovations, Lek, a Sandoz company
	Vidula Kolhatkar, PhD	Pharmacologist, DB II, OB, OGD, CDER, FDA
	Peter Langguth, RPh, PhD	Professor, Johannes Gutenberg University Mainz
	Paulo Paixão, PhD	Member of the MWP, EMA; Assistant Professor, University of Lisbon
	Mohan Krishna Rayeni, MPharm	Scientist-Biopharmaceutics and IVIVC, Sandoz Development Center
	Fang Wu, PhD	Senior Pharmacologist, DQMM, ORS, OGD, CDER, FDA
	Lei Zhang, PhD	Deputy Director, ORS, OGD, CDER, FDA