Revised 08AUG2013

Modeling & Simulation for Medical Products Workshop
September 26, 2013

Register Here

W Hotel | 515 15th Street NW | Washington, DC USA

INTEGRATED APPROACHES TO MODELING & SIMULATION FOR DEVELOPING MEDICAL PRODUCTS AND REGULATORY REVIEW

Drug development and regulatory review has become increasingly challenging and resource intensive. An integrated strategic approach to developing and applying modeling and simulation tools in drug development will enhance decision-making processes. This workshop will examine:

- Novel tools and approaches to accelerate the development of efficacious medicines with optimal benefit/risk profiles
- Successes and lessons learned in the use of modeling and simulation by FDA, industry, and public-private-partnerships
- Challenges & opportunities for these innovative approaches

AGENDA

7:30 am	**Continental Breakfast**	
8:30 am	**Welcome & Opening Remarks**	*Dr. Thomas Colatsky (FDA/CDER)*
8:45 am	**Keynote Panel**	*Moderator: Dr. Vikram Sinha (FDA/CDER)*
	Dr. Issam Zineh (FDA), Dr. Sandra Allerheiligen (Merck), Prof. Meindert Danhof (Leiden University), Dr. Jose Pinheiro (J&J)	
9:45 am	**BREAK**	
10:00 am	**Session I: FDA Perspective on Applying Modeling & Simulation in Regulatory Decision-Making—Successes and Lessons Learned**	*Moderator: Dr. Vikram Sinha (FDA/CDER)*
	▪ Chemistry Models & Impact on Safety Assessment in Drug Development	*Naomi Kruhlak (FDA/CDER)*
	▪ Dose Estimations and Clinical Trial Design	*Yaning Wang (FDA/CDER)*
	▪ Biostatistics Contributions to Modeling & Simulation and Adaptive Trial Design	*Dr. Sue-Jane Wang (FDA/CDER)*
	Panel Discussion: Issam Zineh, Lisa LaVange, Naomi Kruhlak, Yaning Wang, Sue-Jane Wang,	
11:30 am	**Session II: Industry Perspective on Applying Modeling & Simulation in Regulatory Decision-Making and Translational Pharmacology—Successes and Lessons Learned**	

Moderator: Dr. Michael Krams (J&J)

- Quantitative Tools to Support Biomarker Qualification — *Dr. JF Marier (Pharsight)*
- Comprehensive Clinical Trial Simulation Tool for Alzheimer's Disease — *Dr. Brian Corrigan (Pfizer)*
- Combining Patient-Level & Summary-Level Data for Model Development — *Dr. James Rogers (Metrum Research Group)*
- Mechanistic Application of Risk Markers for Prediction of Renal & Cardiovascular Efficacy — *Prof. H.J. Lambers Heerspink (University of Groningen)*

Panel Discussion: Sandy Allerheiligen, Zaven S. Khachaturian, JF Marier, Brian Corrigan, , James Rogers, H.J. Lambers Heerspink

1:00 pm **LUNCH**

2:00 pm **Session III: Future Perspectives for Modeling & Simulation Tool Development & Applications**

Moderator: Dr. Sandra Allerheiligen (Merck)

- Translational Modeling Tools for Combination Drug Development — *Dr. Tawanda Gumbo (U. of Texas)*
- Clinical Trial Simulation Tools for Combination Drug Development — *Dr. Peter Vis (LAP&P)*
- Collaborative Approaches to Mechanistic Modeling — *Dr. Paul Watkins (U. North Carolina)*
- Making Models Publicly Available: Successes & Challenges — *Dr. Tina Morrison (FDA-CDRH)*
- Open-Source Platform for Model & Knowledge Sharing — *Dr. William Gillespie (Metrum Research Group)*

Panel Discussion: Tawanda Gumbo, Peter Vis, Paul Watkins, Tina Morrison, William Gillespie

3:45 pm **Closing Remarks** — *To be announced*

4:00 pm **ADJOURN & NETWORKING**