Workshop
In Vitro to In Vivo Extrapolation for High Throughput Prioritization and Decision Making

U.S. Environmental Protection Agency
Research Triangle Park, North Carolina, USA
February 17-18, 2016

Final Program

— Day 1 —
Wednesday, February 17, 2016

8:00–8:30: **Registration**
Poster presenters hang up posters

8:30–8:45: **Welcome**
Warren Casey, National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM)

8:45–9:15: **The EURL ECVAM Toxicokinetics Report and EURL ECVAM Strategy**
Alicia Paini, European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM)

9:15–9:45: **Workshop Background**
Summaries of Webinars
John Wambaugh, U.S. Environmental Protection Agency (EPA)

9:45–10:00: **Break**

10:00 **Session 1: Application in Risk Assessment: What Do We Need for Decision-making and Prioritization?**

10:00-10:25 **Using In Vitro Data in Quantitative Risk Assessments (QRAs)**
Paul Price, EPA

10:30-10:55 **Interindividual Variability in High Throughput Risk Prioritization of Environmental Chemicals**
Caroline Ring, EPA

11:00–11:25 **Quantitative Considerations of Dose-Response for IVIVE**
Ted Simon, Ted Simon LLC

11:30–12:15: **Lunch**
On your own in EPA cafeteria

12:15	**Session 1 cont'd: Application in Risk Assessment: What Do We Need for Decision-making and Prioritization?**
12:15-12:40	**Toxicokinetics in Risk Assessment: From Predictive Evaluations to Regulatory Testing** *Mike Bartels, The Dow Chemical Company*
12:45-1:10	**Development and Application of Biologically Based Dose-Response Modeling for Pregnancy Conditions: Evaluation of Thyroid Active Chemical Exposure During Sensitive Life Stages** *Annie Lumen, U.S. Food and Drug Administration*
1:15-1:35	**Discussion**
1:35-1:45	**Break**
1:45	**Session 2: Metabolism and Excretion**
1:45-2:05	**Strength and Limitations of In Vitro Xenobiotic Metabolism Assays and In Silico Models** *Stephen Ferguson, National Institute of Environmental Health Sciences (NIEHS)*
2:05-2:30	**In Silico Screening of Primary Clearance Mechanisms** *John Troutman, The Procter & Gamble Company*
2:35-3:00	**In Vitro Models for Quantitative Prediction of Hepatobiliary Clearance** *Kim Brouwer, University of North Carolina at Chapel Hill*
3:05-3:20	**Discussion**
3:20-3:30	**Break**
3:30	**Session 3: In Silico Modeling**
3:30-3:55:	**Predictive Power of PBPK Modeling and In Silico/In Vitro-In Vivo Extrapolation Using GastroPlus™ and ADMET Predictor™ Software Tools** *Grazyna Fraczkiewicz, Simulations Plus, Inc.*
4:00-4:25:	**In Vitro In Vivo Extrapolation and its Applications in Predicting Pharmacokinetic Population Variability** *Alice Ke, SimCyp, a Certara Company*
4:25-4:40	**Discussion**
4:40-5:00	**Day 1 Wrap-up** *Barbara Wetmore, ScitoVation, LLC*
5:00-6:00	**Poster Session and Reception**

— Day 2 —

Thursday, February 18, 2016

8:30–10:00 **Breakout Session 1**

Group A: Toxicokinetic (TK) Model Considerations
Moderators: Annie Jarabek, EPA; Alicia Paini, EURL ECVAM
Group B: In Silico and Non-animal Methods for Obtaining TK Parameters
Moderators: Nisha Sipes, NIEHS; John Wambaugh, EPA
Group C: Application to Risk Assessment and Prioritization
Moderators: Nicole Kleinstreuer, NICEATM; Scott Lynn, EPA

10:00-10:15: **Break**

10:15-11:45: **Breakout Session 2**

11:45–12:45: **Lunch**

On your own in EPA cafeteria
Breakout group moderators meet to coordinate

12:45-1:45 **Breakout Group Reports**

Measureable action items and big-picture area of opportunity

1:45-2:30 **Discussion and Synthesis**

John Wambaugh, EPA

2:30-3:00 **Closing**

Warren Casey, NICEATM