Friday – morning, October 3, 2008

Time	Basic Concepts of pharmacokinetics (PK) and Pharmacodynamics (PD)	Clinical Aspects & Applications of PK/PD	WHOLE DAY BIOANALYTICAL WORKSHOP – Theory and Hands-on
8:00AM	**PK1: Basic concepts in pharmacokinetics** **Dr. Carl Kirkpatrick, 45 min** From human physiology, absorption / sampling sites, and routes of elimination to the clearance & volume of distribution concept	**ClinPK1: Introduction and Overview into PK/PD for patients, Dr. Roger Jelliffe, 45 min** Optimizing individualized patient therapy using nonparametric PK and PD models, multiple model (MM) dosage design, and Bayesian adaptive control.	**Lecture on Liquid Chromatography in biomedical sciences,** **Dr. Matthias Unger, 45 min** Strategies for method development
8:45AM	**PD1: Basic principles in pharmacology** **Dr. Donald Mager, 45 min** Receptor occupancy theory, Hill equation, Examples of effect vs. concentration profiles	**ClinPK2: Overview and comparison of parametric and non-parametric estimation techniques, Drs. Jelliffe & J. Bulitta, 45 min** Differences in algorithms used to estimate parameters of PK/PD models	**Lecture on HPLC coupled with tandem mass spectrometry (LC-MS/MS)** **Dr. Gérard Hopfgartner, 45 min** Strengths, applications, and intricacies of LC-MS/MS for biomedical research
9:30AM	**Case study 1: Group discussion PK1, PD1** **Drs. Kirkpatrick and Mager, 30 min**	**Case study 1: Clinical problems. Solving them using PK/PD Adaptive Control, 30 min** MM dosage design, 4 types of Bayesian model individualization, and MM dosage adjustment.	**Practical Issues of Bioanalytical Problems – How to Approach Assay Development, Drs. Unger & Hopfgartner**
10:00AM	Break (30 min)		
10:30AM	**PK 2: Absorption & Elimination Processes** **Dr. Carl Kirkpatrick, 45 min** Determinants of rate & extent of absorption Hepatic, renal, and other routes of elimination	**ClinPK3: Therapeutic drug monitoring – how does the patient benefit** **Dr. Alexander Vinks, 45 min** How can therapy be optimized by measuring drug concentrations and PK/PD modeling	**Lecture on microdialysis: Measuring unbound concentrations in tissues,** **Dr. Markus Zeitlinger, 45 min** Microdialysis as a powerful and versatile tool to measure unbound concentrations
11:15AM	**PD 2: Pharmacokinetic / Pharmacodynamic Concepts, Dr. William Jusko, 45 min** Overview of basic and more advanced PK/PD models – when to consider which model?	**ClinPK4: Optimizing cardiovascular therapy, Dr. Jelliffe, 45 min** Example for use of modeling and individual therapy optimization (e.g. for digoxin)	**Lecture on bioanalytical techniques: What do capillary electrophoresis (CE) and NMR spectrometry have to offer?** **Dr. Ulrike Holzgrabe, 45 min**
Noon	**Case study 2: Group discussion PK2, PD2** **Drs. Jusko and Kirkpatrick, 30 min**	**Case study 2: Discussion of benefits and applications of PK/PD for patients, 30 min** **Drs. Vinks and Jelliffe**	**Case study 3: Discussion of pros and cons of various bioanalytical techniques, 30 min** **Drs. Zeitlinger and Holzgrabe**
12:30PM to 1:45PM	Lunch break (75 min)		

Friday – afternoon and evening, October 3, 2008

	Basic Modeling & simulation (M&S) techniques	Clinical Aspects & Applications of PK/PD How to implement this approach in real-life	Optimal therapy in special patient groups
1:45PM	**M&S 1: Standard non-compartmental analysis, Dr. Samer Mouksassi, 45 min** Introduction to the most commonly used non-compartmental methods of PK data analysis	**ClinPK5: Therapeutics: optimizing learning about the patient while treating him/her at the same time, Dr. Jelliffe, 45min** How to maximize learning while treating	**Dose optimization for cancer patients** **Dr. Ulrich Jaehde, 40 min** Overview and issues of PK principles and applications for cancer therapy
2:30PM	**M&S 2: Design, analysis, and key aspects of bioequivalence studies, Dr. Helmut Schütz, 45 min** Techniques and critical issues of bioequivalence assessment	**ClinPK6: PK/PD modeling to optimize anti-infective therapy, Dr. Alan Forrest, 45min** Transition from theory to real life: How can a physician / pharmacist apply population PK/PD models at the bedside (HIV patient examples)	**Dose optimization for pediatric patients** **Dr. Alexander Vinks, 40 min** Using PK/PD to optimize therapy in children
3:15PM	**Group discussion: Practical discussion on how to assess bioequivalence** **Drs. Mouksassi and Schütz, 30 min**	**Group discussion: How to implement clinical PK/PD modeling for patient care** **Drs. Jelliffe and Forrest, 30 min**	**Individual differences in effects of psychoactive drugs: Interactions, pharmacogenetics and other factors** **Dr. Julia Kirchheiner, 40 min**
3:45PM to 4:30PM	**Afternoon Break**		
	Compartmental modeling and Population PK/PD data analysis	**Monte Carlo Simulations and Disease Progression Modeling**	**Overview of PK/PD tools for estimation, optimal design, & clinical trial simulation**
4:30PM	**M&S 3: Introduction to Compartmental Modeling and Simulations,** **Dr. Cornelia Landersdorfer, 45 min** Highlighting differences and similarities to non-compartmental techniques	**M&S 5: Monte Carlo Simulations to predict the behavior of a whole patient population** **Dr. Vincent Tam, 45 min** What can we learn from incorporating between subject variability into simulations?	**M&S 7: Overview of PK/PD software tools for estimation and optimal design** **Dr. Jürgen Bulitta, 30 min** The most appropriate / feasible methods for each task – the pros & cons of PK/PD tools
5:15PM	**M&S 4: Concept and basic principles of population PK modeling,** **Dr. Carl Kirkpatrick, 45 min** How to best account for between subject variability & the effect of patient characteristics	**M&S 6: Combining PK/PD with disease progression modeling,** **Dr. Cornelia Landersdorfer, 45 min** Benefits of incorporating natural disease progression and long-term drug effects	**M&S 8: Non-parametric population PK/PD tools for estimation and patient care** **Dr. Roger Jelliffe, 40 min** How to achieve target goals most precisely – an efficient strategy for optimal patient care
6:00PM	**Group discussion: How to apply modeling and simulation of clinical trials** **Drs. Kirkpatrick, 30 min**	**Group discussion: How to integrate PK, PD, disease progression via Monte Carlo sims.** **Drs. Tam and Landersdorfer, 30 min**	**M&S 9: Clinical trial simulation as a tool to design robust and effective clinical trials** **Dr. Samer Mouksassi, 50 min** Pharsight Clinical Trial Simulator Case study

ISAP Workshop – October 4, 2008

Saturday morning

	International Society for Anti-infective Pharmacology: Basic principles and applications
7:45AM	Basic concepts of PK/PD for anti-infectives **Dr. Hartmut Derendorf**, 45 min
8:30AM	The PK/PD indices for anti-infectives – how to use them for optimal therapy, **Dr. Johan Mouton**, 45 min
9:15AM	How to select empiric antibiotic therapy and optimize patient survival **Drs. Thomas Lodise / G. Drusano**, 45 min
10:00AM	Break (30 min)
10:30AM	Chemotherapy and PK/PD of intracellular infections, **Dr. Paul Tulkens**, 45 min
11:15AM	Antibiotic exposure at the infection site – the importance of tissue penetration and protein binding, **Dr. Ursula Theuretzbacher**, 45 min
Noon	Traditional and Modern methods to study bacterial growth and killing *in vitro*, **Dr. Vincent Tam**, 45 min
12:45 to 1:45PM	Lunch break (60 min)

Saturday afternoon

	Clinical Aspects and applications	Experiments & modeling for drug development and optimal patient therapy
1:45PM	PK/PD of anti-infectives in animal infection models, **Dr. William Craig**, 45 min	
2:30PM	Use of Monte Carlo simulations to select susceptibility breakpoints in various patient groups **Dr. Johan Mouton**, 45 min	
3:15PM	Clinical antibiotic development using PK/PD and progression modeling **Dr. Jerome Schentag**, 45 min	Modeling the time course of bacterial growth and killing *in vitro* and *in vivo* **Dr. Alan Forrest**, 45 min
4:00PM	Break (20 min)	
4:20PM	Experimental and Modeling approaches to optimize duration of therapy, **Dr. Vincent Tam**, 45 min	Mechanism-based models for anti-infectives – what do they have to offer, **Dr. Jürgen Bulitta**, 45 min
5:05PM	How to overcome resistance in antibacterial, antiviral and antifungal therapy **Dr. George Drusano**, 45 min	

Each presentation will last about **35 to 40 min** to allow for **5 to 10 min questions & answers**.

Workshop Mentor Team (in alphabetical order):

1. Jürgen Bulitta
2. William Craig
3. Hartmut Derendorf
4. George Drusano
5. Alan Forrest
6. Gérard Hopfgartner
7. Ulrich Jaehde
8. Roger Jelliffe
9. William Jusko
10. Ulrike Holzgrabe
11. Julia Kirchheiner
12. Carl Kirkpatrick
13. Charlotte Kloft
14. Cornelia Landersdorfer
15. Thomas Lodise
16. Donald Mager
17. Johan Mouton
18. Samer Mouksassi
19. Helmut Schütz
20. Vincent Tam
21. Ursula Theuretzbacher
22. Paul Tulkens
23. Matthias Unger
24. Alexander Vinks
25. Markus Zeitlinger