

Organizers
Prof. Hartmut Derendorf
University of Florida, hartmut@cop.ufl.edu

Prof. Francesco Scaglione
University of Milan, francesco.scaglione@unimi.it

Claudia Goller
CG HealthCare and Services, info@Ihre-Apothekerin.net

Italian Society of Pharmacology
Pierluigi Canonico, Novara
Achille Caputi, Messina
Michele Carruba, Milan
Emilio Clementi, Milan
Annamaria Digiulio, Milan
Teresita Mazzei, Florence
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Cesare Sirtori, Milan

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7th Symposium

New Developments in Clinical Pharmacy and Clinical Pharmacology

June 13, 2009
Stresa, Italy



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8:00-9:00 **Registration/Coffee**

9:00-9:30 *Welcome by*

Hartmut Derendorf

University of Florida, Gainesville, FL

Francesco Scaglione

University of Milan, Milan, Italy

Claudia Goller

CG HealthCare and Services, Starnberg, Germany

William Riffie

University of Florida, Gainesville, FL

9:30 *Personalized Medicine – Opportunities and Risks for
Pharmaceutical Industry*

Hans-Günter Schäfer

Boehringer Ingelheim

9:45 *Tuberculosis Drug Development: PK/PD Challenges*

Bernd Meibohm

University of Tennessee

10:00 *Pharmacogenetics and Drug Development*

Dario Cattaneo

Luigi Sacco, University Hospital

10:15 *Current Controversies in Asthma Therapy*

Leslie Hendeles

University of Florida

10:30-10:55 **Break**

10:55 *Design and Application of Biological Therapies Against Urologic
Malignancies*

Johannes Vieweg

University of Florida



Paul Doering MS, Paul Doering is Distinguished Service Professor in the Department of Pharmacy Practice at the University of Florida, College of Pharmacy. He is also Co-director of the statewide Drug Information and Pharmacy Resource Center. Mr. Doering received his B.S. degree in pharmacy from the University of Florida in 1972 and continued his training at the same institution, earning the MS in

Clinical Pharmacy in 1975. Upon graduation, Mr. Doering accepted a position in the University's Department of Medicine as a research assistant where he designed, implemented and evaluated a program of adverse drug reaction monitoring in the obstetric patient. Current teaching responsibilities include: coordinating a Non-prescription Products course for undergraduate pharmacy students, a senior level course in Pharmacotherapy, and an elective course in Drug Abuse. He also guest lectures in a variety of team taught courses in the College of Pharmacy and other Health Center colleges. Paul has very strong ties with the practice of pharmacy, having been a practicing pharmacist both in the hospital and community setting. A member of many local, state, and national pharmaceutical societies, Paul is a Past-President of his local pharmacy association. For his hard work with students, Paul has been recognized four times as Teacher of the Year for the College of Pharmacy. In March, 1990, Mr. Doering was awarded Fellowship status in the APhA's Academy of Pharmacy Practice and Management. In 1993, Mr. Doering received one of two Teaching Incentive Awards given to College of Pharmacy faculty at the University of Florida. Mr. Doering was promoted to Distinguished Service Professor in April 1995, the University's highest honor which can be awarded to a faculty member. He is the first professor in the College of Pharmacy's 70-plus year history to be recognized in this way.



Sven Normann, PharmD is the Associate Dean for Distance, Continuing, and Executive Education for the College of Pharmacy at the University of Florida. He also serves as Director of the Working Professional Pharm.D. program. He is a Clinical Associate Professor in the Department of Pharmacotherapy and Translational Research. Dr. Normann obtained his B.S. in Pharmacy degree from Creighton University and his Pharm.D. from the University of Florida. He completed a PGY-1 Residency in

Hospital Pharmacy at the Mayo Medical Center / Saint Marys Hospital in Rochester, Minnesota and served as a PGY2-3 Fellow in Clinical Toxicology at the University of California, San Diego and University of California, San Francisco. Prior to joining the faculty at UF, Dr. Normann served as the Director of the Florida Poison Information Center in Tampa and Louisiana Poison Center at the LSU Medical Center in Shreveport. He has served on the Board of Directors of the American Association of Poison Control Centers and is a charter Diplomate of the American Board of Applied (Clinical) Toxicology. His professional interests include clinical toxicology, medication safety, and distance education. He also has special interests in International Pharmacy Education and the Role of the Pharmacist in Public Health Emergencies.

- 11:15** *Alternative Medicine for Kidney Stones*
Saeed Khan
University of Florida
- 11:30** **Presentation of GlobalGator Award**
- 11:45** *Preclinical Development of Biopharmaceuticals*
Mathias Locher
Merck Serono
- 12:00** *Vaccinology: A New Area of Clinical Pharmacology?*
Francesco Scaglione
University of Milan
- 12:30-13:30** **Lunch**
- 13:30** *Historical Perspectives on Research in the UF College of Pharmacy*
Michael McKenzie
University of Florida
- 13:45** *Potential of St Johns Wort as Anti-Stress Medication*
Veronika Butterweck
University of Florida
- 14:00** *Absolute Bioavailability and Metabolism of Echinacea tetraenes after Intravenous and Oral Single Doses to Rats*
Karin Wölkart
University of Graz, Austria

- 14:15** *Current Concepts in Clinical Pharmacology*
Markus Müller
 Medical University Vienna
- 14:30** **Break**
- 15:00** *Application of Stratified Medicine in Clinical Drug development as Advantage for Patients*
Andreas Kovar
 Merck Serono
- 15:15** *Integration of Genomic and Transcriptomic Data: A Boost for Biomedical Research*
Marion Deuter
 IMG M Munich
- 15:30** *International UF Clinical Pharmacy Degree Program – Past, Present, Future*
Sven Normann
 University of Florida
- 16:00** *New Approaches in Pharmacy Education – US View*
Tom Munyer
 University of Florida
- 16:15** *New Approaches in Pharmacy Education – German view*
Charlotte Kloft
 Martin Luther University of Halle



Charlotte Kloft, PhD, Charlotte Kloft is a Full Professor at the Martin-Luther-Universitaet Halle-Wittenberg, Institute of Pharmacy, Germany. She is leading the Department of Clinical Pharmacy which is involved in undergraduate teaching in the Pharmacy curriculum (Staatsexamen, Diploma) and graduate training as well as patient-oriented research: Her current research interest focuses on exploring the complex interaction between patient and drug to guide rational dosing recommendations for (subgroups of) patients. Dr. Kloft did her Habilitation and venia legend in Clinical Pharmacy, from the Freie Universitaet Berlin, Germany. From 1997-1999 she joined Dept. DMPK of Hoechst Marion Roussel (today: sanofi-aventis) after she earned her PhD from the Freie Universitaet Berlin with highest possible honours. She has received several awards including the Ernst-Reuter-Preis and is currently a member of the international and local organizing committees of the Population Approach Group Europe (PAGE), also preparing the Annual Meeting in Berlin in 2010. She currently is a member of several scientific societies and of the Scientific Board of the German Pharmacopoeia Committee at Federal Institute for Drugs and Medical Devices (BfArM). She also is a member of editorial boards and reviewer for several biomedical and pharmaceutical journals. In 2008 as one of the chairs, she launched the Graduate Research Training (GRT) Program 'Pharmacometrics & Computational Disease Modelling (*PharMetriX*)', a novel joint initiative in Germany of the Martin-Luther-Universitaet Halle-Wittenberg and the Freie Universitaet Berlin with six major research-driven pharmaceutical companies.



Marion Deuter studied Pharmacy at the Ludwig-Maximilian University of Munich, Germany, from 1995 to 2000. In 2000, she spent 6 months of her pharmaceutical residency at Prof. Derendorf's lab at the University of Florida, and thus became a Global Gator. From 2001 to 2005, she prepared her doctoral thesis at the molecular biology department of the cancer research unit of Roche Diagnostics GmbH, Penzberg, Germany. The focus of her work was to analyze drug-related

effects by monitoring changes in gene expression of tumor cells by using whole-genome microarrays and real-time PCR. In 2005, Marion joined the service provider company IMG Laboratories GmbH located in the biotech cluster Martinsried near Munich, Germany. After holding the position of Head of Laboratory for several years, she has recently switched to the position of Head of New Technologies and Product Development. Her areas of expertise include gene expression analysis, SNP genotyping, microRNA analysis, sequencing and bioinformatics.



Tom Munyer, MS, is a Clinical Associate Professor, Director of Active Learning and coordinates three of the six pharmacotherapy courses at the University of Florida College of Pharmacy. He is a graduate of the University and has been teaching at the College for thirty years. He worked with others to develop innovative, high tech, instructional design techniques utilizing

learner-centered, active engagement techniques to prepare our students for their professional clinical roles. He has 12 years experience in critical care and nutrition support, six years experience in software design and development, and 12 years experience in epilepsy and pharmacy administration.

16:30 *Pregnancy Labeling for US Drug Products: It's Not as Easy as A-B-C*

Paul Doering
University of Florida

Group Photo

20:00 **GatorFest**

Late Night: **Nightcap**



Francesco Scaglione, MD, graduated from Faculty of Medicine, University of Milan, Italy, in 1978 with first class honours. From 1978 to 1980 he was Junior medical doctor in Internal Medicine at Military Hospital in Milan. From 1980 to 1983, Assistant Professor at INRCA – Chest Hospital, Casatenovo Brianza, Como, Italy. In 1983 he received his PhD in Physiology and Respiratory Diseases. From 1983 to 1986, he was Visiting Professor at Department of Pathology, Locarno, Switzerland, and from

1986, Assistant Professor at Department of Pharmacology, Chemotherapy and Toxicology, University of Milan, Italy. In 2000-04 Dr. Scaglione was general secretary of the International Society of Antiinfective Pharmacology. He is Professor of Clinical Pharmacology at school of medicine and Co-Chairman of the Department of Pharmacology, Chemotherapy and Toxicology, University of Milan, Italy and currently he is President of the Italian Society of Chemotherapy. He belongs to eleven other Societies, Associations and Colleges. He publishes widely, speaks regularly at international meetings, is currently supervising six PhD students and holds several University appointments (e.g. as Professor of Clinical Pharmacology). Dr. Scaglione's research activity involves the clinical pharmacology, the immune response to infections and the action of natural extracts on the immune system.



Hans Günter Schäfer, PhD, received the Pharm.D. and PhD degrees from the University of Muenster, Germany. After a post-doctoral fellowship at the University of Florida, Gainesville, USA, he started his industrial career in 1989 at the Department of Clinical Pharmacology at Bayer AG, Germany. In 1996 he joined Eli Lilly and Company (UK) where he was responsible for Clinical Pharmacokinetics and Clinical

Pharmacology Operations Europe. In July 2000, Dr. Schaefer joined Boehringer Ingelheim (Germany), where he is presently Director, Clinical Pharmacokinetics & Pharmacodynamics. His current research interest is in the integration of biomarker and pharmacogenetic data with PK/PD modelling to optimise early clinical development and profiling of drug development candidates. His responsibilities also include the implementation of BI's DNA Bank and the development of the necessary IT-solutions.



Markus Müller, MD, is a Professor and Head of the Department of Clinical Pharmacology of the Medical University Vienna/Vienna General Hospital in Austria. He has received his M.D. from the University of Vienna Medical School with highest possible honours (sub auspiciis praesidentis rei publicae). He was trained in Emergency Medicine,

Oncology, Endocrinology, Infectious Diseases, Chemotherapy and Angiology and is board certified for Internal Medicine, Clinical Pharmacology and Emergency Medicine. He holds the position of a Professor for Internal Medicine and Clinical Pharmacology. Dr. Müller serves as a European Expert for the European Agency for the Evaluation of Medicinal Products (EMA) in London, UK and is a frequent speaker at international meetings and a reviewer for several biomedical and pharmaceutical journals and scientific societies. He has published over 150 original articles in the field of clinical pharmacology and has received several awards including Tanabe Award of the American College of Clinical Pharmacology (ACCP) in acknowledgement of innovations in clinical pharmacology trials and the Billroth Award of the Austrian Board of Physicians.



Andreas Kovar, PhD, joined Merck KGaA in 1997 as Clinical Pharmacokineticist and has held several scientific and managerial positions within R & D functions including Head of Global Clinical Pharmacology and Pharmacokinetics. Currently he is Vice President of Global Exploratory Medicine at Merck Serono. He graduated in pharmacy and holds a PhD in Medicinal Chemistry. Before joining Merck he worked as a research fellow and postdoc at the University of Tübingen and for 2 years at the University of Florida, Gainesville. Since 2001 he is member of the

board of regents of the Association of Applied Human Pharmacology and is a Fellow of Clinical Pharmacology of the American College of Clinical Pharmacology.



Veronika Butterweck, PhD, research focus is on Experimental Phytopharmacology which basically is the investigation of activity profiles of herbal extracts as well as isolated compounds and their mechanism of action.

A specific area focuses on the investigation of plants with activities on the central nervous system (CNS). One particular part concentrates on the development of herbal antidepressants as well as anxiolytics. In order to identify potential active compounds of herbal extracts, phytochemical fractionation procedures are used in combination with pharmacological testing. Besides research on the CNS, an additional emphasis of our work is on the development of new therapeutic concepts for the treatment of metabolic disorders. In particular, this concerns application-oriented research of phytomedicines for the treatment of type II diabetes, arthritis (gout) and kidney stones. An additional research program focuses on interactions between herbal medicines / dietary supplements and synthetic medications as well as on the pharmacokinetics of natural products.



Karin Wölkart, Mag. Pharm. Dr.rer.nat., studied pharmacy at the Karl-Franzens-University, Graz, Austria, and obtained the PhD degree in 2005 with phytochemical and pharmacological investigations on *Echinacea angustifolia* DC. as well as clinical studies and new insights in the molecular mode of action. Since that time she is a scientific associate in sciences and teaching at the Institute of Pharmaceutical Sciences, Department of Pharmacognosy, Graz.

In 2008 she was PostDoc within a “FWF, Erwin-Schroedinger scholarship” at the Department of Pharmaceutics, University of Florida, Gainesville. In 2005 she received the “Alfred Vogel Award, in Switzerland”, in 2006 the “Josef-Krainer Scientific Award, in Austria” and the “Egon Stahl Award from the Society of Medicinal Plant Research, in Finland”. Her scientific work is in the field of biopharmaceutical especially pharmacokinetic and herb-drug interaction studies with focus on herbal medicinal products. She is author of 13 original papers, 3 reviews and 1 book chapter, peer-reviewer of various journals and member of the Society of Medicinal Plant Research (GA) and the Austrian Pharmaceutical Society (OePhG).



Bernd Meibohm, Ph.D., FCP, is a Professor of Pharmaceutical Sciences and Associate Dean for Graduate Programs and Research at the College of Pharmacy, The University of Tennessee Health Science Center, Memphis, TN. He received his B.S. in pharmacy and Ph.D. in pharmaceuticals from the Technical University Carolo-Wilhelmina, Braunschweig, Germany. After completion of a clinical pharmacology research fellowship at the University of Florida in 1997, he joined the faculty of the University of South Carolina, and in 1999 the University of

Tennessee. Dr. Meibohm’s scientific interests include chronic inflammatory pulmonary diseases, pediatric pharmacotherapy and the application of quantitative modeling and simulation techniques in preclinical and clinical drug development, with specific focus on biotech drugs. His research work has attracted more than \$5 million in extramural funding as principal and co-investigator and has resulted in over 60 scientific papers and book chapters, two textbooks, 110 abstracts, and over 80 invited scientific presentations to national and international audiences. Dr. Meibohm is a Fellow of the American College of Clinical Pharmacology (ACCP) and recipient of the 2000 ‘New Investigator Award in PK, PD and Drug Metabolism’ from the American Association of Pharmaceutical Scientists (AAPS). He is currently the 2009 Chair-Elect for the ‘Pharmacokinetics, Pharmacodynamics and Drug Metabolism’ (PPDM) section of AAPS, and has recently started to serve a five year term on ACCP’s governing Board of Regents. Dr. Meibohm is also serving as associate editor for *The AAPS Journal*, as section editor for ‘Pharmacokinetics and Pharmacodynamics’ for the *Journal of Clinical Pharmacology*, and is a member of the editorial boards of the *Journal of Pediatric Pharmacology and Therapeutics*, the *Journal of Pharmacokinetics and Pharmacodynamics*, *Les Annales Pharmaceutiques Françaises* and *Die Pharmazie*.



Dario Cattaneo PharmD, PhD, received his Pharmacy degree in 1996 and specialisation in Pharmacology (2001) both awarded by the University of Milan. In 2000 specialization in “Pharmacological Research” at the Mario Negri Institute for Pharmacological Research (IRFMN) and in 2005 PhD degree awarded by

the Open University of London, UK. Currently, Dr. Cattaneo is working in the Unit of Clinical Pharmacology of the “Luigi Sacco” University Hospital, Milan. Dr. Cattaneo’s research interest include pharmacokinetics, pharmacodynamics and pharmacogenetics of immunosuppressants, antiviral agents and hypolipidemic drugs; study of secondary forms of dyslipidemia; polypharmacological approaches for the treatment of chronic kidney diseases; assessment of humoral response as predictor of acute or chronic rejection after organ transplantation. He is the author of nearly 60 scientific articles published in peer-review journals, five book chapters, and 40 abstracts presented in different international congresses. He participated as invited speaker in several meetings organized by national and international societies (American Society of Transplantation, International Association of Therapeutic Drug Monitoring and Clinical Toxicology, American Society of Nephrology, etc).



Michael McKenzie PhD, is currently the Senior Associate Dean for Professional Affairs in the UF College of Pharmacy. He has administrative responsibilities in student and academic affairs. He is a professor in the Department of Pharmacotherapy and Translational Research. In the past, he was the first clinical pharmacist to work with the pediatric service at Shands Hospital and Clinics in Gainesville, Florida. He initiated and taught

an elective course in pediatric pharmacy for many years. He presently coordinates and teaches in an honors seminar course, “In Search of Magic Bullets,” which is offered to UF honors students. His pharmacy education includes a B.S in Pharmacy degree from Samford University in Birmingham, Alabama, a Masters in Hospital Pharmacy degree from the University of Florida, and a Ph.D in Clinical Pharmacy from Purdue University in West Lafayette, Indiana. He completed an ASHP accredited hospital pharmacy residency at the University of Alabama Hospitals and Clinics in Birmingham. He is a member of the American Pharmacists Association, the American Association of Colleges of Pharmacy, the Florida Pharmaceutical Association, and the Florida Society of Health-System Pharmacists. He is a member of Rho Chi Honorary Pharmaceutical Society, and he has served as president of Phi Lambda Sigma, the national pharmacy leadership society.



Mathias Locher, PhD, is Head of Global DMPK at Merck Serono. Before joining Merck Serono in 2007, Mathias worked for 4 years in Biotechnology at Micromet AG in Munich as Vice President Preclinical Development. Micromet develops special antibody constructs the so called BiTE molecules, activating T cells to attack tumor cells. This was a total new area of research working suddenly with biologics. At ASTA

Medica where Mathias started his career in pharmaceutical industry in the Department of Biological Research Biochemistry in 1990 he worked for 14 years with NCEs and peptides. Starting as laboratory manager for metabolism and toxicokinetics, Mathias was appointed in 1996 as Head of Biological Research Biochemistry and in 2001 as Vice President Early Phase development. It was during the time at ASTA Medica where Mathias met Hartmut and they started a close collaboration with regard to the PK/PD modelling for the LHRH antagonists and where Hartmut and his people did a great job with their PK/PD model to justify the dose. Finally ASTA Medica succeeded to get the approval for Cetrotide in Europe and the US for the use in *in vitro* fertilization, the first approved LHRH antagonist.



Leslie Hendeles, Pharm.D., is a Professor in the College of Pharmacy and also in the Department of Pediatrics at the University of Florida. He earned his Pharm.D. degree at the University of Southern California. Among his current research interests are the improvement of adherence to asthma medications and delivery of inhaled drugs to young children. He is a consultant to FDA's Pulmonary Division, and previously served on the Coordinating Committee of NIH's Asthma Education

Program, as well as CDC's Expert Panel on Asthma Guidelines for Emergency Medical Services. Dr. Hendeles provides advice on drug therapy and teaches in the Pediatric Pulmonary Clinic at the University of Florida.



Johannes W. Vieweg, M.D., F.A.C.S., is a Board certified urologic surgeon and is the Professor and founding Chairman of the Department of Urology and the Wayne and Marti Huizenga Eminent Scholar Chair in Urology at the University of Florida, College of Medicine. In addition, he is serving as attending surgeon at the Malcom Randall VA

Medical Center. Dr. Vieweg received his MD from the University of Munich, Germany, and completed urology residencies at both the University of Ulm, Germany, and in the Department of Surgery, Division of Urology at Duke University Medical Center. Dr. Vieweg served as Vice-Chair of Urology Research at Duke and was appointed to his current leadership position at the University of Florida in July, 2006. Dr. Vieweg is an internationally recognized authority in urologic oncology and has a longstanding, focused interest in cancer immunology and gene-based therapies. In addition to his administrative and clinical responsibilities, he is spearheading a productive research program focusing on the development of novel treatments for patients with advanced urologic malignancies. Dr. Vieweg's projects also involve the development and testing of "targeted therapeutics", as well as improved prediction models for therapeutic success. Reflective of the quality of his research program are multiple manuscripts published in outstanding peer-reviewed journals and continuous NIH funding for over eight years.



Saeed R. Khan, PhD, is a Professor in the Department of Pathology, Immunology and Laboratory Medicine in University of Florida College of Medicine. Dr. Khan's research involves investigation of kidney stone. Dr. Khan has so far published over 300 articles, 130 in refereed journals. He has served and

continues to serve on various panels reviewing research grant applications. He has received the University of Florida Research Achievement Award, College of Medicine Faculty Research Prize in Basic Science as well as the University of Florida Research Foundation Professorship. He has given keynote addresses, and plenary and state of the art lectures at conferences and symposia both at national and international meetings including meetings in Australia, Britain, China, France, Germany, India, Italy, Japan, Pakistan, South Africa, Sweden, Switzerland and Taiwan. Dr. Khan has had significant involvement in national and international professional associations, serving as President of the Florida Society for Microscopy; President of the ROCK (Research on Calculus Kinetics) Society and Member of the Nominations Comm of the Society for Leukocyte Biology. He regularly reviews manuscripts for scholarly journals and is currently Associate Editor of Urological Research. Dr. Khan has served as Director, Center for the Study of Inflammatory Host Defense and Tissue Injury and is currently Director, Center for the Study of Lithiasis and Pathological Calcification. He is a Past President of the College of Medicine Faculty Council, and has served as Chair of the Faculty Senate Nominations Comm., Academic Advisory Council, and Policy Council on Research and Scholarship in addition to being Chair of the Senate Honorary Degrees Committee. Currently he is a member of the Senate Academic Policy Council.