The current Ph.D. in Pharmaceutical Sciences graduate program is offered by the Department of Pharmaceutics. The departmental faculty has decided to use 'track' method for accommodating the diversity of the Department's graduate population, its multi- and interdisciplinary.

The focus of the Department of Pharmaceutics, which houses the Center for Drug Discovery, differs sufficiently from that of other departments as to justify a specialization. The uniqueness of the department is evident in present research activities which encompass basic, applied and clinical investigations in the areas of Biopharmaceutics and Pharmacokinetics, Pharmaceutical Biotechnology, Pharmaceutical Analysis, Drug Delivery, and Drug Discovery. Specifically, Biopharmaceutics and Pharmacokinetics, encompasses the absorption, distribution, metabolism and excretion of drugs in animals and humans, and the relationship between drug concentration and effect; Pharmaceutical Biotechnology includes molecular biology, immunology, and aspects of the delivery of peptide and protein drugs; Pharmaceutical Analysis involves the application of spectroscopy, chromatography, extraction, electrophoresis, immunoassays, and radioisotope assays to drug determination; Drug Delivery includes physical, biological and chemical approaches to drug delivery, formulation and evaluation of dosage forms and Drug Discovery is associated with receptor-oriented/retrometabolic drug design, computer assisted drug design, chemical/physical approaches to controlled drug delivery, pharmacokinetic-pharmacodynamic correlation approach to improving therapeutic index for active pharmaceutical ingredients.

- Objectives of the Ph.D. Program
- Faculty
- Adjunct Faculty
- Governance
- Recruitment of Students
- Admission Procedures
- Financial Assistance
- Selection of Discipline for Degree and Major Professor
- Supervisory Committee
- Curriculum
- Qualifying Examination
- Final Examination
- Specific Requirements for the Master of Science in Pharmacy Degree
The **objectives** of the Ph.D. program in the Department of Pharmaceutics are:

- To provide a foundation in the pharmaceutical sciences in general, as well as in the specific tracks identified, with emphasis on pharmacokinetics, biopharmaceutics, pharmaceutical analysis, pharmaceutical technology/drug delivery, pharmacodynamics, pharmaceutical biotechnology, and drug design and discovery.
- To educate individuals capable of conducting independent research and with in-depth specialized knowledge in one of the above areas and to provide a solid educational, technical and experiential foundation for students in the industrial, academic, governmental or other arenas.
- To provide an environment that nurtures and stimulates the research interests and the intellectual advancement of students and faculty, including a forum for scientific and professional discussion.

**FACULTY**

**Nicholas Bodor, PhD,**  
Graduate Research Professor, Emeritus  
Director, Center for Drug Discovery

Design of drugs with improved therapeutic index, based on retrometabolic concepts, design of new chemical and physical delivery systems, computer assisted drug design, drug transport and metabolism, and theoretical mechanistic organic chemistry. Ongoing research is performed in all of the areas mentioned.

**Hartmut Derendorf, PhD,**  
Distinguished Professor of Pharmaceutics and Chair

Correlation of pharmacokinetic and pharmacodynamic behavior of drugs (corticosteroids, analgesics, antibiotics); analysis of drugs and metabolites in biological fluids by HPLC-pharmacodynamic evaluations by pharmaco-electroencephalography (EEG); pharmacokinetics in sickle cell patients.

**Guenther Hochhaus, PhD,**  
Professor of Pharmaceutics,

Dr. Hochhaus' research includes the development of novel analytical techniques for the measurement of drugs in biological fluids by chromatographic and immunological techniques-the metabolism, pharmacokinetic and pharmacodynamic properties of opioid peptides, pharmacokinetic/dynamic (PK/PD) behavior of anti-asthmatic drugs and their relevance for the formulation of targeted pulmonary delivery systems.

**Lawrence Lesko, PhD, FCP,**  
Professor
Lawrence J. Lesko, Ph.D., F.C.P. has been leading UF’s new Center for Pharmacometrics and Systems Pharmacology in the interdisciplinary Institute of Therapeutic Innovation at the UF Research and Academic Center in Lake Nona (Orlando) since July 2011.

Before joining UF, Dr. Lesko worked nearly 20 years in the Food and Drug Administration’s Center for Drug Evaluation and Research as the Director of the Office of Clinical Pharmacology. He was also Chair of the Clinical Pharmacology Coordinating Subcommittee of the FDA’s Medical Policy Coordinating Committee and authored or co-authored numerous Guidance for Industry, and started the FDA’s Voluntary Genomics Data Submission Program and Mechanistic Drug Safety Program. Lesko has published more than 200 peer-reviewed scientific publications and is a frequent invited national and international speaker in clinical pharmacology, personalized medicine, pharmacometrics and systems pharmacology. His research interests include drug development and regulatory science, quantitative clinical pharmacology and pharmacogenomics.

In 2011, Lesko received the Gary Neil Prize for Innovation in Drug Development from the American Society of Clinical Pharmacology and Therapeutics (ASCPT). He also received the Coriell Scientific Leadership Award for Personalized Medicine (2010), the Rawls-Palmer Progress in Medicine award from ASCPT (2007), the University of North Carolina Institute for Pharmacogenomics and Individualized Therapy Award for Clinical Service (2007), and the Nathanial B. Kwit Distinguished Service Award for Clinical Pharmacology from the American College of Clinical Pharmacology (2007). Lesko served as President of the American College of Clinical Pharmacology in 2004-2006. He is a Fellow in the Japanese Society for the Study of Xenobiotics, American College of Clinical Pharmacology and the American Association of Pharmaceutical Scientists. He is Board Certified in Clinical Pharmacology and a registered pharmacist.

Cary Mobley, PhD,
Clinical Associate Professor

Use of liposomes for pulmonary delivery and as oral vaccine adjuvants. Conceptual integration of the pharmacy curriculum.

Anthony Palmieri III, PhD, RPh,
Assistant Scholar,
Graduate Coordinator

Dr. Palmieri’s major responsibilities include licensing of pharmaceutical and life sciences intellectual property. Palmieri holds a BS and MS in pharmacy from the University of Rhode Island and the Ph.D. from the University of Georgia. Prior to his present position he was at The Upjohn Company for sixteen years. Palmieri was Professor of Pharmacy at the University of Wyoming. He is the author of numerous scientific, academic, and historical papers. He served as the Laboratory Editor for the third edition of the Handbook of Pharmaceutical Excipients. Palmieri is very active on the national level of Kappa Psi Pharmaceutical Fraternity and is currently the national vice-president. Palmieri is past chairman of APRS. Currently he is Chair-elect of the Basic
Michael A. Schwartz, PhD,
Professor of Pharmaceutics,
Dean Emeritus

Dr. Schwartz will lecture in graduate courses related to dosage forms and drug stability in the program.

Stephan Schmidt, PhD,
Assistant Professor

After receiving his B.S. in Pharmaceutical Sciences, Dr. Schmidt received his license to practice as a pharmacist in Germany in 2005. After earning his UF doctorate degree, he joined the Division of Pharmacology at the Leiden/Amsterdam Center for Drug Research in the Netherlands as a post-doctoral fellow in January 2009. He was a member of the Dutch Top Institute Pharma mechanism-based PK-PD modeling platform under the supervision of Prof. Meindert Danhof. In January 2012, Dr. Schmidt rejoined the University of Florida as an Assistant Professor at the Center for Pharmacometrics and Systems Pharmacology in Lake Nona (Orlando). His primary research interest is on the development of mechanism-based disease system models. Affiliations

- American Association of Pharmaceutical Scientists (AAPS)
- American College of Clinical Pharmacology (ACCP)
- Paul-Ehrlich Society for Chemotherapy (PEG).

He published his work in 10 peer reviewed journals including the British Journal of Clinical Pharmacology, the Journal of Pharmaceutical Sciences, Clinical Pharmacokinetics, and Antimicrobial Agents and Chemotherapy. Dr. Schmidt is also the lead author of a book chapter on disease progression analysis, published in 2011 as part of an AAPS series on advancing Pharmaceutical Sciences. In 2010, he received the PEG thesis award for his work on “Pharmacokinetics/Pharmacodynamics of oxazolidinones and beta-lactams.”

Sihong Song, PhD,
Associate Professor

Dr. Song's interests are in 1) improvement of safety and efficiency of rAAV vector by understanding molecular mechanisms of persistence and integration of the AAV genome in mammalian cells and 2) the use of recombinant Adeno-Associated Virus (rAAV) vectors mediated gene transfer to develop gene therapy approaches for common diseases such as diabetes and arthritis.

Adjunct Faculty

Adjunct faculty will be selected by the faculty of the department based on the suggestion of
individual faculty member(s) and a departmental ballot. The role of adjunct faculty is to give
guest lectures in graduate courses offered by the department upon mutual agreement between
the course coordinator and the adjunct faculty, and to advise students in graduate research (The
adjunct faculty, the student, and the chair of the supervisory committee should decide the level
of involvement by the adjunct faculty). Participation in supervisory committees by an adjunct
faculty will be governed by the guidelines in the current Graduate Catalog of the University of
Florida.

Marijke H. Adams, PharmD, PhD MH Adams & Associates, Inc
madams@mhadamsassoc.com

Dr. Adams received her PhD in Pharmacy & Pharmaceutics from the Virginia Commonwealth
University, Richmond VA in 1991. The same year, she was awarded her PharmD degree. She
currently holds a pharmacy practice license in both Florida and North Carolina. Dr. Adams is a
member of several scientific organizations including but not limited to AAPS, ACCP and ASHP,
American Society of Health System Pharmacists. In addition, she is an Adjunct Assistant Professor
at Nova Southeastern University, Ft. Lauderdale, FL. She is the president and principal scientist
for MH Adams and Associates Inc., Davie FL. Services include providing pharmacokinetic, drug
development, medical and regulatory writing, and education/training to meet client needs.
Pharmacokinetic services include study- and submission-related activities (eg, protocol design,
study monitoring, data analysis, report writing). Drug development services include clinical
development plans. Writing services include study protocols and Phase 1 reports, Investigators
Brochures, regulatory submission documents (eg, IND, NDA), and publications. Education/training services include drug development process, Good Clinical Practice (GCP), and
Good Manufacturing Practice (GMP).

Vikram Arya, PhD, FCP
FDA
vikram.arya@fda.hhs.gov

Dr. Vikram Arya is a Senior Clinical Pharmacology Reviewer in the Office of Clinical Pharmacology,
Center for Drug Evaluation and Research (CDER), FDA. Vikram earned his Ph.D. in Pharmaceutics
from the University of Florida in 2003. He has several publications in peer reviewed journals and
has presented at various national and international conferences. He is a Fellow of the American
College of Clinical Pharmacology (ACCP) and was recently elected to serve on the Board of
Regents in ACCP. He holds an Adjunct Clinical Professor (Special Title) appointment in the
Department of Pharmacy Practice at Mercer University, Atlanta, GA and Adjunct Assistant
Professor appointment in the Department of Pharmaceutical Sciences at the University of
Tennessee. He serves as a Section Editor in the Journal of Clinical Pharmacology (JCP), as an
Editorial Board Member for JCP and International Journal of Clinical Pharmacology and
Therapeutics (IJCPT), and as a peer reviewer for several other clinical pharmacology journals.
Dr. Barrett is Associate Professor of Pediatrics and Pharmacology at the Children’s Hospital of Philadelphia (CHOP) and University of Pennsylvania. He is also the Director of the Laboratory for Applied PK/PD within the Clinical Pharmacology and Therapeutics Division at CHOP. Prior to joining CHOP, Dr. Barrett spent 13 years in the pharmaceutical industry most recently at Aventis Pharmaceuticals where he was Global Head of Biopharmaceutics supporting late stage development. He received his B.S in Chemical Engineering from Drexel University in 1986 and his Ph.D. in Pharmaceutics from the University of Michigan in 1990 under Dr. John G. Wagner. He has been a faculty member of the Pharmaceutical Education and Research Institute (PERI) as a lecturer for the Pharmacokinetics and Nonclinical Statistics training courses since 1992. and was a member of both the PhRMA and FDA Expert Panels on Individual and Population Bioequivalence. Dr. Barrett has co-authored over 50 manuscripts and has given 35 invited lectures on a variety of topics related to clinical drug development. He founded the Mid-Atlantic Population Approach Users Group in 1992 and is a member of the Advisory Boards of the East Coast Population Approach Group, the American Association of Pharmaceutical Scientists (AAPS) Bioequivalence and Population Pharmacokinetics Focus Groups, and the Innaphase Corporation. Dr. Barrett is a member of AAPS, ASCPT, ACCP and ASPET and was former Chair of the Delaware Valley Drug Metabolism Discussion Group. He was elected to Fellow of the American College of Clinical Pharmacology in 2000 and was awarded the Tanabe Young Investigator Award in 2002. Dr. Barrett was also recently elected to the Board of Regents of ACCP and as Vice-Chair of the Clinical Sciences Section of AAPS.

**Focus at Children’s Hospital of Philadelphia:**

Dr. Barrett’s current efforts in conjunction with the mission of the Clinical Pharmacology and Therapeutics Division are focused on the investigation of sources of variation in pediatric pharmacokinetics and pharmacodynamics. Applied clinical pharmacologic investigation coupled with modeling and simulation strategies are pursued with the intention of developing rational dosing guidance in various pediatric populations for both marketed and exploratory compounds. Clinical trial simulation is to be utilized prospectively to explore design dependencies and parameter sensitivities. Dr. Barrett also directs the Laboratory for Applied PK/PD which is focused on the development of pharmacometric approaches to advance PK/PD, novel biomarker development and disease progression modeling.

**Research Interests / Current Efforts**

“The focus of my research is really driven by two objectives: (1) the utilization of PK/PD modeling and simulation techniques to establish links between drug exposure, actions, and therapeutic outcomes and (2) pursuit of therapeutic drug monitoring (TDM) in conjunction with modeling and simulation strategies to improve the management of pediatric drug therapy within CHOP.” The list below describes ongoing efforts and research topics I am currently exploring. – Development of physiologically-based PK models to explore maternal to fetal drug transfer, –
Population-based PK model development in support of ongoing/proposed study drugs (Heparin, Midazolam and Actinomycin-D), – Data warehousing and data mining approaches in bio- and medical informatics, – Development of novel biomarkers for the investigation of heparin and LMWH patient management through anticoagulant PK/PD, – Exploration of physiologic – developmental PK/PD models which predict drug exposure in various pediatric populations based on drug substance /physiochemical characteristics in conjunction within adult PK/PD behavior, – Exploration of trial design characteristics for optimal pediatric drug trials focused on safety, PK, PK/PD and/or efficacy through clinical trial simulation.

Robert Baughman, PharmD, PhD
MannKind Corporation
rbaughman@mannkindcorp.com

Dr. Baughman is currently Vice President, Experimental Pharmacology at MannKind Corporation in Danbury, CT. He received his undergraduate degree in Biology from Loyola University, Los Angeles, and his Pharm.D. in 1978 and Ph.D. (Biopharmaceutics) in 1982 from the University of California, San Francisco. Dr. Baughman held pre-clinical and clinical research positions at Lederle Laboratories, Genentech, Penederm, Cholestech, and Emisphere Technologies prior to this tenure at MannKind. His current research interests include developing and optimizing novel dosage forms and characterizing the disposition of therapeutic peptides and proteins. He has conducted clinical studies with more than 15 macromolecular drug products, including novel, non-parenteral formulations of insulin, growth hormone, parathyroid hormone, heparin, and calcitonin. His more than 130 published works are focused on the pharmacokinetics and delivery of recombinant and synthetic drug products. He is an active member of the American Diabetes Association and the American Association of Pharmaceutical Scientists (AAPS). He was elected Chairman of the AAPS Biotechnology section and to a 3-year term as the Association’s Treasurer, as well as serving as a member of the AAPS Executive Council. He sat on the Advisory Board of the American College of Clinical Pharmacology and the Editorial Board of the International Journal of Clinical Pharmacology and Therapeutics. He has held an adjunct faculty appointment in the College of Pharmacy, University of Florida since 1988. He is lives in Ridgefield, CT, with his wife Barbara and their six children.

Robert Bell, PhD
Drug and Biotechnology Development, LLC
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Drug & Biotechnology Development, LLC (D&BD) is a comprehensive consortium of experienced clinicians, pharmaceutical scientists, regulatory strategists and business development experts that provide product and business development assistance and solutions for the pharmaceutical, biotech, medical product and related industries. From project conception to product launch, D&BD provides a focused approach to the pharmaceutical and clinical development of drugs, devices and biologics for regulatory submissions. D&BD has extensive experience with all phases
of product development, including pre-clinical, clinical (Phase I-IV), CMC (analysis, formulations, process, production), outsourcing, CRO oversight and regulatory interactions, document preparation, review and filings

Marcus Brewser, PhD
Janssen Research Foundation
mbrewste@janbe.jnj.com

Marcus E. Brewster is a Vice President and Scientific Fellow at Janssen Research and Development (the Pharmaceutical Companies of Johnson & Johnson) based in Beerse, Belgium. He is a member of the Drug Product Development department within the Pharmaceutical Development and Manufacturing Sciences division and acts as the Single Point of Contact (SPOC) for the group. He was previously global head of Pharmaceutical Sciences and the Chief Scientific Officer of the Chemical and Pharmaceutical (ChemPharm) division. He has worked with Johnson & Johnson for 15 years. Dr. Brewster has focused his research interests on solubilizing delivery technologies for the development of bioavailable formulations for poorly water-soluble drugs and drug candidates including the use of nanotechnology, solid solution and dispersion approaches, novel surfactant and polymeric micelles and complexing agents including chemically modified cyclodextrins. He has also been involved with developing sustained release dosage forms based on biodegradable polyester devices as well as the development of prodrugs, soft drugs, supersaturating and other chemical delivery systems. Dr. Brewster is a Fellow of the American Association of Pharmaceutical Scientists, a Director-at-Large of the Controlled Releases Society (2012-2014) as well as a former member and co-chairman of the Board of Scientific Advisors (2007-2009) and a former co-chairman of the Symposium/Workshop Committee for that organization, an Editor of the Journal of Pharmaceutical Sciences (drug delivery and biopharmaceutics), a member of the Editorial Board of Die Pharmazie, a former theme editor for Advanced Drug Delivery Reviews, a member of various scientific societies and organizing boards (including the European Symposium for Controlled Drug Delivery, the European Drug Absorption Network and the International Symposium on Cyclodextrins) and the recipient or co-recipient of various recognitions including the J&J Excellence in Science Award (in 1998 and 2006), the J&J Encore Award (2008, 2009, 2010, 2011, 2012), the J&J Standards of Leadership Award (2010, 2011, 2012), an Innovative Analytical Research Prize presented by FACC S (2003), a PARC Prize for Innovation in Pharmaceutical Analysis (2007) and the European Journal of Pharmaceutics and Biopharmaceutics Best Paper Award (2010). Dr. Brewster has published over 250 peer-reviewed journal articles, book chapters and proceeding, has co-edited a monograph on solvents systems and their use for AAPS Press/Springer, presented over 370 meeting abstracts and was named as inventor or co-inventor on approximately 75 patents. He has also delivered more than 60 plenary or invited lectures and 60 other oral presentations. Dr. Brewster received his B.S. from Mercer University in 1978 and his Ph.D. from the University of Florida in 1982 in the field of Pharmaceutical Sciences. He was a visiting scientist at the Weizmann Institute of Science from 1996 to 1997. Dr. Brewster is an adjunct Professor at the University of Florida, College of Pharmacy and has served on numerous Ph.D. student committees and juries.
Dr. Veronika Butterweck is Professor at the Department of Pharmatechnology at the University of Applied Sciences in Muttenz/Basel Switzerland. She received her B.S. (1993) and PhD (1997) in Pharmacy from the University of Münster, Germany. Dr. Butterweck was a Postdoctoral Fellow at the National Institutes of Mental Health, Bethesda, Maryland, in 1999 and 2001. She received the *venia legendi* (Habilitation) for Pharmacology in 2003 from the University of Münster, Germany. From 2003 until 2011 she joined the the College of Pharmacy, Department of Pharmaceutics at the University of Florida as a faculty member. Dr. Butterweck is Editor of Planta Medica and was a member of the Expert Committee ‘Dietary Supplements/Botanicals” of the United States Pharmacopoeia (USP) from 2005-2010. She is also a member of the Board of Directors of the Society of Medicinal plant and Natural Products Research and Chair of the Permanent Committee for Biological and Pharmacological testing of Botanicals. Her research focuses on the development of new therapeutic concepts based on herbal medicines. In particular her laboratory has emphasized herbal medicines for the treatment of anxiety, depression and diabetes. In addition, Dr. Butterweck’s research also emphasizes the pharmacokinetics of natural products as single compounds and in comparison with herbal extract.

Jack Cook  
Pfizer Inc  
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Jack Cook, Ph.D. is Vice President, Clinical Pharmacology Specialty Care at Pfizer, Inc., Groton, CT. Additionally, Dr. Cook is an Adjunct Professor in College of Pharmacy at the University of Michigan. He received the A.A.S degree in Industrial Chemistry Technology (1978), and B.S. degrees in Applied Mathematics (1981) and Pharmacy (1981) from Ferris State College; and the Ph.D. degree in Pharmaceutics from the University of Michigan (1987). Dr. Cook started his career with Sterling Drug Inc. in Albany, NY in 1981. In 1987 he joined Parke-Davis which later became Pfizer, Inc.

Dr. Cook’s areas of technical expertise are in biopharmaceutics, pharmacokinetics, pharmacodynamics, modeling and statistics. He is a member of the American Association of Pharmaceutical Scientists and on the Board of Directors for the Drug Delivery Foundation. His current interests include improving therapy by optimizing drug delivery and the use of modeling and simulation to make rational decisions in the development of drugs. He has published 51 original research articles and 3 book chapters.

Geoffrey A. Cordell, PhD  
Professor Emeritus University of Illinois  
pharmacog@gmail.com
Professor Geoffrey A. Cordell, Professor Emeritus at the University of Illinois, obtained his Ph.D. in synthetic natural product chemistry at the University of Manchester in 1970. After two years as a NATO postdoctoral fellow at the Department of Chemistry, M.I.T., he joined the College of Pharmacy, University of Illinois at Chicago (UIC). A Professor since 1980, he served as a Department Head for 12 years and as Interim Dean of the College of Pharmacy for almost three years, as well as holding several other senior administrative positions at the Department, College, and Campus levels.

He is the author of over 600 research publications, book chapters, comprehensive reviews, and professional publications, and is the editor of 37 books, including 29 volumes in the series “The Alkaloids: Chemistry and Biology”. He was the author of “Introduction to Alkaloids: A Biosynthetic Approach”, and is presently writing two books on alkaloids. He is a member of the Editorial Advisory Board of twenty-five international scientific journals, and is a former President and an Honorary Member of the American Society of Pharmacognosy, one of only 14 world-wide. He has offered over 350 invited lectures at scientific meetings, universities, and research institutes around the world.

He is an elected Fellow of the Royal Chemical Society, the Linnean Society of London, and the American Association of Pharmaceutical Scientists. He also holds positions as an Honorary Professor at Sichuan University, Chengdu, China, the Foreign Director of the Sichuan Academy of Chinese Medical Sciences also in Chengdu, China, and Director, Committee of Examination and Evaluation of the World Federation of Chinese Medical Societies, Beijing, China. In addition he is a Visiting Professor at Universities in Bangladesh, Brazil, Japan, Malaysia, and Peru, His research is focused on the sustainability of medicinal agents, new strategies and methods for the analysis of biologically active natural products, the use of vegetables as chemical reagents, and enhancing the quality control of traditional medicines for improved global health care. He is presently assisting groups in several countries around the world develop their natural product research programs.

Staffan Edsbäcker, PhD
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Married, 2 children; Chemical engineer, M.Sci 1979; Joined Astra 1980 (Dept of Metabolism and Pharmacokinetics); Ph D 1986 (“Studies on the metabolic fate and pharmacokinetics of budesonide”); Assoc Prof., Experimental Clinical Pharmacology, Faculty of Medicine, Univ of Lund 1997-current; Section Head from 1990 – March 1999; Scientific Adviser at Experimental Medicine, AstraZeneca R&D Lund for 6 global AstraZeneca projects March 1999-June 2001; Secondment as Sr Director, Experimental Medicine, AstraZeneca Pharmaceuticals LP, Wilmington USA 2001-2003; Currently Senior Scientific Director for respiratory projects at AstraZeneca Respiratory & Inflammation Innovative Medicines Unit in Molndal, Sweden. Preclinical experience in metabolism (tissue homogenates, isolated perfused tissues); Human pharmacology experience in traditional pharmacokinetics (exploratory and documentative); Lung, nasal and gut
deposition studies using various techniques (modelling, scintigraphy, charcoal block etc); Interaction and tolerability studies; Scientific marketing activities; Regulatory issues (Experimental Medicine responsibility for 6 NDAs). Staffan has published about 40 full length original papers, 12 book chapters and reviews, and about 50 abstracts dealing with the deposition, pharmacokinetics and systemic pharmacodynamics of topical corticosteroids in healthy subjects and patients with asthma, rhinitis and inflammatory bowel diseases. Invited lecturer at several conferences. Tutor for 2 PhD students, one of whom defended his thesis in October 1998.

Ronald Evens, PharmD
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Ronald Evens is President of MAPS 4 Biotec, Inc, consulting to the biotechnology segment of the pharmaceutical industry concerning medical affairs roles of medical communications and education, product information, and clinical trials (peri-approval and post launch). Dr. Evens is clinical professor at University of Florida, College of Pharmacy, specializing in the science and business of product development in the biopharma industry. Ron serves on the Company Review Committee for the University of Florida Sid Martin Biotechnology Incubator; and the Frontiers Committee of the American College of Clinical Pharmacy Research Institute. Invited presentations exceed 150 at national and state associations or universities. Publications are over 100, including editor of 2 books, 15 book chapters, and over 40 refereed journal articles. Previously (13 years, 1989-2002) at Amgen, he created and was Senior Director and Head of Professional Services Department with a professional staff of 145. Professional Services was responsible for medical communications/education, marketing support & oversight, phase 2 & 4 studies, field based clinical liaisons, medical science liaisons, and product information for marketed and pipeline products. Also, he created and was Senior Director and Head of PeriApproval Research at Amgen. Prior to Amgen, Dr. Evens was Associate Director, Clinical Research and Medical Services at Bristol-Myers Co. (1984-89); Associate Professor and Acting Chairman of Department of Pharmacy Practice at University of Tennessee Health Sciences Center, Memphis, TN (1981-84); Associate Professor & Director of Drug Information Center at University of Texas at Austin, College of Pharmacy, and University of Texas Center for Health Sciences, College of Medicine, San Antonio (1974-81); staff pharmacist at E.J. Meyer Memorial Hospital associated with University of Buffalo. Dr. Evens received his B.S in Pharmacy from the University of Kentucky.

Robert Gieseler, MD, PhD
RGieseler@lettherebehope.org

Dr. Robert Gieseler received his MD, and his PhD in immunology from Georg-August University (Göttingen, Germany) in 1991, graduating Magna Cum Laude. Dr. Gieseler is Chief Scientist for HIV/AIDS, lymphoma, and leukemia for LTBH Medical Research Institute, Beverly Hills, CA. Before
joining LTBH he was a Research Consultant for Essen University Clinic, Essen Germany, Senior scientist working on Graves disease and thyroid associated ophthalmopathy. Dr. Gieseler has supervised numerous medical students and PhD candidates. He has co-authored several articles and has been invited to give talks at international conferences in Germany and Austria. He is on the Directory Board of the Dept. of Clinical Chemistry and Lb. Diagnostics at Essen University, Germany and on the Scientific Advisory Board of Let There Be Hope Medical Research Institute and the Thyroid League of Germany (SLD). Dr. Gieseler’s was the technical artist in J.H. Peters, H. Baumgarten (eds.): Monoclonal Antibodies. Springer, New York 1992, as well as the preceding German edition.

Joga Gobburu  
University of Maryland  
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Dr. Gobburu is Professor with School of Pharmacy and School of Medicine, University of Maryland, Baltimore, MD, USA. He held various positions at US FDA between 1999 and 2011. Under his leadership, a Division of Pharmacometrics (DPM) was formed at the FDA and several policies were established. He is a world-recognized scientific leader in the area of quantitative disease models and their application to decisions. Dr. Gobburu is best known for transforming the field of Pharmacometrics across the world into a decision-supporting science. He also established a Pharmacometrics Fellowship program at the FDA. He received numerous FDA awards such as Outstanding Achievement Award. He also received Outstanding Leadership Award from the American Conference on Pharmacometrics (2008), Tanabe’s Young Investigator Award from American College of Clinical Pharmacology (2008). Dr. Gobburu is on the Editorial Boards of several journals. He published over 60 papers and book chapters.

Mario Gonzalez, PhD  
P’Kinetics  
Mario@PKineticsIntl.com

Dr. González is President of P’Kinetics International, Inc. specializing in biopharmaceutics and pharmacokinetics research. Dr. González was previously President of GloboMax Américas and prior to that was Director of Biopharmaceutics and Pharmacokinetics at Schering Research, Miami (formerly Key Pharmaceuticals, Inc). His research has concentrated on the pharmacokinetic and pharmacodynamic evaluation of extended-release oral and transdermal drug delivery systems as well as in vitro/in vivo correlations. Prior to joining the pharmaceutical industry, Dr. González was on the Pharmacy faculty at Purdue University with teaching and graduate research responsibilities in clinical pharmacokinetics. Currently he is an adjunct Professor in the University of Florida College of Pharmacy. Dr. González has been active in AAPS since its inception and was Chair of the Pharmacokinetics Section in 1995. He also served on the organizing committees of the first four AAPS/FDA SUPAC Workshops and was Co-Chair of the Organizing Committee for the first Pharmaceutical Congress of the Americas held in March, 2001.
Dr. Gonzalez is also a member of the Controlled-Release Society, the American College of Clinical Pharmacology, and the American Society of Health-System Pharmacists. He serves on the editorial advisory boards of the European Journal of Pharmaceutics and Biopharmaceutics and the International Journal of Clinical Pharmacology and Therapeutics. Dr. Gonzalez was appointed to the USP Biopharmaceutics Expert Committee for 2005-2010, the Dosage Forms Expert Committee for 2010-2015, and was elected as a Fellow in Clinical Pharmacology by the American College of Clinical Pharmacology

Ulrike Graefe-Mody, PhD
Boehringer Ingelheim Pharma Gmbh & Co
Ulrike.Graefe-Mody@boehringer-ingelheim.com

Dr. Graefe-Mody is working in Clinical Development/Medical Affairs as Deputy Therapeutic Area Head Metabolic Diseases at Boehringer Ingelheim’s headquarters in Germany. She is heading the Early Clinical Development Team which is responsible for the global clinical development of internal projects and clinical due diligence activities for licensing opportunities. Prior to her current role, she was part of the clinical pharmacokinetics/pharmacodynamics group led by Hans Guenter Schaefer. Before joining Boehringer Ingelheim, Dr. Graefe received her Diploma in Biology in 1997 and PhD degree in Pharmaceutical Biology in 2001 from the University of Wuerzburg, Germany. Her thesis focused on the clinical pharmacokinetics and bioavailability of phenolic compounds in phytomedicines, which was carried out in cooperation with Prof. Hartmut Derendorf at the University of Florida, Gainesville, FL. In 2001, Dr. Graefe-Mody received the Carl-Wilhelm-Scheele Award of the German Pharmaceutical Society for outstanding dissertations in Pharmaceutical Sciences. Dr. Graefe-Mody has published over 30 articles, abstracts, a book chapter and presentations with focus on clinical pharmacology of cardiometabolic drugs.

Pravin R. Jadhav, PhD
FDA
Pravin.Jadhav@fda.hhs.gov

Pravin R Jadhav is Director of Modeling and Simulation at Merck Sharp and Dohme. He is responsible for planning and executing advance research to lead high quality and cost effective drug development programs from discovery through commercialization. Before joining Merck and Co., he was Team Leader and Expert Regulatory Scientist in the Division of Pharmacometrics of the Office of Clinical Pharmacology (OCP) at the US food and Drug Administration (FDA). He has worked on more than 100 New Drug Applications and 150 Investigational New Drug applications covering aspects of exposure–response to aid in important regulatory decisions such as drug–drug interactions, dose adjustment in special populations, evidence of effectiveness, benefit/risk and labeling issues. He covered various therapeutic areas such as anti-viral, anti-infective, transplant, reproductive and urology, cardiovascular and renal, dermatology, and medical counter measures (MCM) products in 9 years at FDA. Pravin represented OCP as an
internal expert on clinical pharmacology issues in pediatric drug development advising all the Office of New Drugs (OND) divisions as an appointed member of the Pediatric Review Committee (PeRC), a committee mandated by the congress. He was also a member of the IRT-QT team as a reviewer, and TQT guidance and BP risk guidance working groups. He has more than 25 publications in peer reviewed journals and 40 oral presentations at international conferences. He has received several awards and honors at the FDA, including outstanding service award in 2008 and special citation for innovative analysis on telaprevir and boceprevir new drug applications in 2011.

Pravin received his BPharm and MPharm from India, and a PhD in Pharmaceutical Sciences from the Medical College of Virginia Commonwealth University in May 2006. He is a Fellow of the American College of Clinical Pharmacology and holds an adjunct faculty appointment in the College of Pharmacy at University of Florida.

Ray Jurgens, PhD
Pfizer Oncology
Raymond.W.Jurgens@pfizer.com

“Ray is a Director in Pfizer’s Regional Medical & Research Specialist group in Oncology. His expertise is product development, project management, development and management of clinical trials, and formulation of drug development strategies with key opinion leaders. Located in his regional office in Florida, he works with large academic cancer centers and institutes in the Southeastern US. His current focus is in the area of solid tumors. Prior to joining Pfizer, he had similar positions at Ligand Bio Pharmaceuticals in LaJolla, California, and Berlex Laboratories in their Oncology divisions. Earlier in his career, he worked in oncology developing a novel multi drug resistance (MDR) compound at CytRx, a small biotech company in Atlanta. His industry experience also includes various clinical and project management positions at Solvay Pharmaceuticals and Mallinckrodt Medical. Ray lives near Clearwater, Florida. He received his Bachelor of Science degree in Pharmacy from Drake University and his PhD in Pharmaceutical Sciences/Drug Development from the University of Florida. He has over 40 publications and 3 patents.”

Kiman Kim
Korea Food & Drug Administration
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Mr. Kiman Kim is a deputy director of herbal medicine management team at Korea Food and Drug Administration (KFDA). He is responsible for herbal medicine approval, pharmaceutical company inspection, and international collaboration at KFDA. He received his bachelor of pharmacy degree from Seoul National University, Republic of Korea in 1983, and got a master of pharmaceuticals degree from the same university in 1985. He was a senior researcher developing drug dosage forms and drug delivery systems at the research center of Yuhan Pharmaceutical Co. in Korea (1985—1990). He was with the Seoul Metropolitan Government as a pharmaceutical
inspector (1993—1996), and has been working for KFDA since 1996. Since 1993 he has inspected hundreds of pharmaceutical companies in Korea and in the world as a pharmaceutical inspector. He researched the harmonization activities in the drug approval process between the USA, Europe and Asia with particular emphasis on biopharmaceutics and pharmacokinetics under the supervision of Dr. Hartmut Derendorf at University of Florida (2002—2004). He published a paper with Dr. Derendorf concerning the differences in the drug pharmacokinetics between East Asians and Caucasians and the role of genetic polymorphisms in 2004. He is interested in building the international harmonization of herbal medicine approval and study.

Michael King, PhD  
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My interests are broadly focused on degeneration in the brain, its functional consequences, and the development of therapeutic strategies that can counteract pathological processes and promote restorative mechanisms. Current projects involve developing models of and therapeutics for the major dementing neuropathologies associated with aging: stroke, Alzheimer’s, and Parkinson’s disease. We have 20 years experience developing and using adeno-associated viral vector technology to make preclinical gene delivery models of inherited and sporadic tauopathies, and inherited amyloidopathies, as well as age-related memory dysfunction. We have also used this gene transfer approach to try to counteract tau, amyloid, injury, and memory-related pathology by discrete intracranial expression of degradative enzymes and neurotrophic factors. Previous studies related to memory and aging include a comprehensive electrophysiological analysis of hippocampal synaptic function and plasticity across the lifespan of adult rats prior to the age when mnemonic dysfunction emerges. The laboratory has expertise in a variety of anatomical techniques including stereology and quantitative histometry, and also employs behavioral assays of cognitive and motor performance. Biochemical and molecular analyses of protein and gene expression, and intracellular signal transduction, complement anatomical, behavioral, and electrophysiological methods. Active collaborations include studies on simulated blast shock-induced brain injury, septohippocampal development, stereotypy related to environmental impoverishment, the development of epilepsy, histological validation of phenomena derived from magnetic resonance imaging techniques, and mechanisms relating neuropathology and behavior in localized brain tauopathy.

Sriram Krishnaswami, PhD  
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Dr. Sriram Krishnaswami is an Associate Director in Clinical Pharmacology at Pfizer Global R&D based in Ann Arbor, MI. He received his B.S. in Pharmacy in 1996 from the Birla Institute of Technology and Science, Pilani, India and Ph.D. in Pharmacokinetics/Pharmacodynamics in 2000 from the University of Florida, Gainesville. Dr. Krishnaswami is responsible for representing the clinical pharmacology function in development teams and during interactions with regulatory
authorities. His current research activities include designing dose-finding strategies using modeling and simulation for new chemical entities in the inflammation/dermatology therapeutic area where treatments for diseases such as rheumatoid arthritis, psoriasis and osteoarthritis and prevention of allograft rejection are pursued. Dr. Krishnaswami has published over 30 articles, abstracts, a book chapter and presentations with focus on PK/PD modeling and pediatric pharmacology. He is chair-elect of the AAPS modeling and simulation focus group and peer reviews manuscripts for the Journal of Clinical Pharmacology.

Michael Kurowski, PhD, MD
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Dr. Michael Kurowski, became a Licensed Pharmacist in 1977 and then went on to study Pharmaceutical Chemistry and received his PhD from the Freie Universität Berlin in 1980. He continued his education, receiving his MD from Friedrich Alexander Universität, Erlangen-Nuremberg, Germany in 1986. In 1989 he was Privatdozent, Senior Lecturer for Pharmacology and Toxicology at the Friedrich Alexander Universität, Erlangen-Nuremberg, and then in 1992 became a Specialist for Clinical Pharmacology, Charite, Humboldt Universität, Berlin. In addition to being Co-editor of the Journal Pharmacotherapy, Dr. Kurowski has been a consultant to the community of practicing physicians and Ciba-Geigy, a member of the “Drugs Commission”, Chair, University Hospital, and is an Associate Professor of Pharmacology and Toxicology, Martin Luther Universität Halle Wittenberg. Dr. Kurowski has received numerous awards and fellowships for his work. Dr. Kurowski has been involved in clinical studies and analytics of analgesic and novel antiretroviral compounds since 1997 at the Private Practise Laboratory Medicine and was a Founder Therapia GmbH. He supervises not only PhD candidates but also medical students who are required to write a thesis in Germany. In addition to more than 50 publications in prestigious scientific journals he published 3 books.

Richard Lalonde
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Richard is currently the Executive Director and Head of Clinical Pharmacokinetics and Pharmacodynamics at Pfizer Global Research and Development in Ann Arbor, Michigan. Prior to joining Pfizer (formerly Parke-Davis/Warner Lambert) in 1998, he was Senior Scientific Director at Phoenix International Life Sciences (now MDS) in Montreal, Canada. From 1984 to 1991, Richard was Assistant Professor then Associate Professor and Vice Chairman for Research at the University of Tennessee, Memphis. From 1980 – 1984 he worked at the University of Ottawa Health Sciences Centre in Ottawa, Canada. His research over the past 25 years has been focused on how to integrate pharmacokinetic and pharmacodynamic information to provide improved drug therapy in patients. He is a fellow of the American College of Clinical Pharmacology and the American College of Clinical Pharmacy and a member of the Editorial Board for Clinical Pharmacology and Therapeutics. Richard is a graduate of the University of Minnesota (Pharm.D.)
Nicola Luciani, BS
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Mr. Nicola Luciani is a Registered Pharmacist with the Ontario College of Pharmacy, having received his Bachelor of Science Degree in Pharmacy from the University of Toronto in June 1994. He currently holds the position of Pharmacy Manager with Dell Pharmacy in Hamilton, Ontario, Canada and has been working for Dell since September 1994. Mr. Luciani is an accomplished Compounding Pharmacist specializing in Veterinary Medicine and Advanced Sports Medicine. Mr. Luciani also holds a Doctorate of Acupuncture from Medicina Alternativa, received in April 2000. He has additional special interests in Nutrition, Anti-Aging and Botanical Medicine. He is currently a Board Member of SportPharm Pharmaceuticals, California, USA. Mr. Luciani is a Consultant and Lead Facilitator for Medisca Network Inc. for Certificate Programs in Pharmacy specific to Pharmaceutical Compounding; accredited by and offered at the University of Florida College of Pharmacy.

Maureen A. McKenzie, PhD
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Maureen A. McKenzie, Ph.D. is the Chief Executive Officer of DENALI BioTechnologies, Inc. Dr. McKenzie has almost 20 years of experience in biotechnology as an entrepreneur, researcher and executive, and founded the first and only company in Alaska dedicated to pharmaceutical and nutraceutical discovery and development from boreal territories. DENALI BioTechnologies focuses on plants, microbes, and marine organisms that thrive in harsh habitats, with special emphasis on novel molecules from psychrophiles (“cold-lovers”). Dr. McKenzie was Affiliate Assistant Professor in the Department of Physiology and Pharmacology at the College of Veterinary Medicine of Iowa State University, Ames, in 1994, and was an Assistant Professor of Chemical Biology and Pharmacognosy and member of the Laboratory for Cancer Research in the College of Pharmacy at Rutgers, The State University of New Jersey, New Brunswick, from 1990-1993. From 1989-1990, she was a Research/Teaching Specialist in the Departments of Biochemistry and Environmental and Community Medicine of the University of Medicine and Dentistry of New Jersey-Robert Wood Johnson Medical School, Piscataway, New Jersey. Dr. McKenzie was a Staff Fellow Scientist in the Diabetes Branch of the National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Bethesda, Maryland, from 1987-1989. Prior to graduate school, she was a Microbiologist for the Mobil Oil Corporation, Princeton, New Jersey, from 1979-1981. Dr. McKenzie received a Diabetes Research and Education Foundation Fellowship in basic research from the Hoechst-Roussel Corporation (1990-1992), The New Jersey State Commission for Cancer Research -Ciba Geigy Corporation Award for Scientific Excellence in Cancer Research (1992), and the Epsilon Award for Teacher of the Year in the
College of Pharmacy at Rutgers University (1993). She was selected by the American Chemical Society in 1993 as a Preceptor for Science Experience for the Economically Disadvantaged. In 1994, she was chosen by the Des Moines Register as an Iowa “Up and Comer” for extraordinary leadership in business. In 1995, she received the Linda K. Neuman Award for the Professions by the Quad-Cities Women’s Encouragement Board, and was honored as a “Woman of Spirit and Note” in the community. She served on the Board of Directors of the Quad-Cities Chapter of the American Red Cross in 1995. She has authored or co-authored numerous peer-reviewed articles, patents and is the editor-in-chief of the *Encyclopedia of Medicinal Plants* scheduled for publication in 2006. Dr. McKenzie holds a Ph.D. in Biochemistry from a joint program of Rutgers, the University of Medicine and Dentistry of New Jersey and Princeton University (1987), a M.S. in Food Science from Rutgers (1982) and a B.S. in Nutrition/Food Technology from Iowa State University (1978).

**Melanie Pecins-Thompson, PhD**  
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Dr. Thompson received her B.S. from University of Florida in 1989, and her Ph.D. in Pharmaceutical Science from the University of Florida in 1993. She held a research position at the Oregon National Primate Research Center. While at the Oregon National Primate Research Center, Dr. Thompson received a National Research Service Award which funded her postdoctoral studies. She was also a recipient of A Women in Endocrinology travel award. Her primary research interests are the effects of steroid hormones on serotonin neural function. She has also taught Endocrinology at Portland State University. Dr. Thompson is married with three children ages 3, 5 and 10.

**Marcus Mueller, MD**  
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Markus Müller, M.D. is Professor and Head of the Department of Clinical Pharmacology of the Medical University of Vienna / Vienna General Hospital (AKH) in Austria. He received his M.D. from the University of Vienna and 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 currently serves as Vice-Rector at the Medical University of Vienna / Vienna General Hospital (AKH). He is internationally renowned for the development of clinical microdialysis in drug development and his expertise in clinical vaccine development. He has published over 200 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. His current research interests comprise the development of PET tracers for drug distribution studies, pharmacogenetics and vaccine
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Education in Pharmacy (1962 – 1966) and Food Chemistry (1966-1968) at the University of Freiburg/Germany. PhD (Pharmacognosy) Freiburg, 1971; habilitation (Pharmaceutical Biology) Freiburg, 1976; assoc. Professor of Pharmaceutical Biology, Techn. Univ. of Braunschweig/Germany 1977-1986; full Professor and chair of Pharm. Biology and Phytochemistry, Univ. of Münster/Germany, 1986-2004. Since Oct 2004 Prof. emeritus.; Dr.h.c. of the Ovidius University, Constanța, Romania (2004). Honorary member of the Society of Medicinal Plant and Natural Product Research (GA; 2005). V.E.Tyler Award of the American Society of Pharmacognosy (ASP; 2009); Dr.h.c. of the Maha Sarakham University in Thailand (2010). Scientific areas: Phytochemistry, physiological activity and biopharmaceutical aspects of traditionally used medicinal plants and their constituents. Biochemistry and physiology of secondary constituents of plants and insects, in particular the cyanogenic compounds; >210 papers in these fields; >180 lectures; >140 posters together with coworkers and students. Teaching experiences: Analytics of natural products and plant secondary constituents; Phytochemistry and biochemistry of nature-derived drugs; Pharmacology of crude drugs and plant derived compounds; Pharmacognosy (microscopy) of crude drug material; Morphology and anatomy of plants. Member of the Committee of Experts “Pharmaceutical Biology (Pharmacognosy)” of the German Pharmacopoeia (1987-2008); Member of the “Board of Directors” of the Society of Medicinal Plant and Natural Product Research (1981-2005) and the “Board of Directors” of the Gesellschaft für Phytotherapie (Society of Phytotherapy; 1995-2004); Deputy-member of the Commission E of the Federal Institute of Medicinal Products and Medical Advices (2002-2004). Coeditor of Planta Medica (1983 – 1992); Editor in Chief of Planta Medica – Natural Products and Medicinal Plant Research” (1993 – 2004), since then Senior Editor of Planta Medica.

Emil Pop, PhD
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Chairman at the First World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology; International Advisory Board, International Conferences on Drug Optimization via Retrometabolism; Inaugural Member of the Florida Center for Heterocyclic Compounds Industrial Advisory Board; Guest Editor of a “hot topic” issue of Current Pharmaceutical Design; Member Editorial Advisory Board Letters in Drug Design & Delivery. Scientific Activity: 131 publications, 23 patents, 131 presentations. Expertise: organic, pharmaceutical, medicinal and theoretical chemistry. Drug design, synthesis and evaluation of novel drugs, prodrugs, chemical drug delivery systems; chemistry of synthetic cannabinoids. Basic research scale-up product and process development.

Dr. Pop was the recipient of the 2011 Global Gator Award in Graz, Austria.

Shashank Rohatagi, PhD
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Dr. Shashank Rohatagi is a Senior Director in Translational Medicine and Clinical Pharmacology Department at Daiichi Sankyo Pharma Development (DSPD), Edison, NJ, since August, 2004. I am currently responsible for the pharmacokinetic and pharmacodynamic analysis (population and two-stage) of new drug candidates and line extension projects and oversee all 14C labeled pharmacokinetic studies. Previous to joining DSPD, Dr. Rohatagi was a Director, Drug Metabolism and Pharmacokinetics at Aventis Pharmaceuticals in Bridgewater, N.J, since 1996. He received a PhD degree in Pharmaceutics from the University of Florida, Gainesville, FL in 1995 and an MBA degree from St. Joseph’s University in 2000. His main interest is in elucidating pharmaceutical principles especially pharmacokinetics and pharmacodynamics in the field of asthma, oncology, immunology, cardiovascular disease, diabetes and central nervous system (CNS). He has currently published more than 50 peer-reviewed articles, given more than 60 poster or oral presentations at various national and international meetings. He is currently a member of American Association of Pharmaceutical Scientists (AAPS), American College of Clinical Pharmacology (ACCP), American Society of Clinical Pharmacology and Therapeutics (ASCPT) and American Academy of Allergy, Asthma, and Immunology (AAAAI). He is a Fellow of American College of Clinical Pharmacology. He serves on the Editorial Board of the Journal of Clinical Pharmacology and peer review manuscripts for the International Journal of Clinical Pharmacology and Therapeutics.
Srikumar Sahasranaman, PhD
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Dr. Srikumar Sahasranaman is a Development Scientist in Clinical Pharmacology and a Pharmacology Sub-Team Leader at Genentech, San Francisco. He received his B.S. in Pharmacy from the Birla Institute of Technology and Science, Pilani, India; M.Sc. from National University of Singapore and Ph.D. in Pharmaceutical Sciences from the University of Florida, Gainesville. Dr. Sahasranaman has over eight years of clinical pharmacology experience in the development of small molecules and biologics in multiple therapeutic areas including neuroscience, respiratory and oncology. His current research focuses on translational, clinical and pharmacometric approaches to understand the PK and PD of targeted small molecule agents and antibody drug conjugates in oncology. He has several publications in peer reviewed journals and is a member of ACCP, ASCPT and AAPS

Stephen Smith, MD
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Dr. Steven R. Smith earned his medical degree from the University of Texas Health Science Center in San Antonio, Texas, in 1988. He completed a residency in internal medicine at Baylor University Medical Center in Dallas, Texas in 1991. He subsequently completed at two-year fellowship in clinical endocrinology and metabolism at the Ochsner Clinic and Hospital in New Orleans, LA. Before coming to Florida Hospital, he was a faculty member at Pennington Biomedical Research Center for 15 years. Dr. Smith’s work bridges the gap between cell/molecular biology and clinical care. This approach is known as translational medicine, and involves translating discoveries in the basic sciences into the clinic and using clinical knowledge to direct the basic scientist. His research is focused on obesity, diabetes and the metabolic origins of cardiovascular disease. He is specifically focused on how individuals differ in their ability to adapt to diets high in fat and understanding how obesity leads to type 2 diabetes. Using the translational medicine approach, Dr. Smith discovered that many obese people have an inability to burn fat and require a new system to increase metabolism. Most importantly, the discovery that the inability to burn fat is programmed into muscle cells provides a novel way to identify and test new treatments for obesity and diabetes. In the clinic, Dr. Smith has a special interest in the identification and development of drugs for the treatment of obesity and diabetes. His translational work demonstrated that each person is unique at the molecular level, suggesting new ways to match therapies to the individual; this is the goal of the new field of “personalized” medicine. In his research career, Dr. Smith has published more than 100 peer-reviewed scientific manuscripts, reviews and chapters and is active in physician education.
Dr. Sullivan has been in the field of drug delivery for the past 13 years with emphasis being placed on increasing the effectiveness of drugs and decreasing side effects. Areas of therapeutic applications have included infectious disease (HIV, HSV and Hepatitis), arthritis and cancer. The drug delivery vehicles have included both liposomes and polymers for small molecular weight, such as doxorubicin and large molecular weight drugs, such as oligonucleotides and plasmids. For the past 6 years, his research efforts have applied this technology toward the development of non-viral gene delivery systems. Non-viral gene delivery systems consist of plasmid DNA encoding a therapeutic gene isolated from bacteria and formulated with either cationic lipids or polymers yielding transfection complexes. The cationic lipid based transfection complexes were developed for transfection of tumor endothelial cells for the purpose of inhibiting tumor angiogenesis. A combination of peptide targeting to receptors on tumor endothelial cells and control of therapeutic gene expression by proliferating endothelial cell promoters are being developed to yield selective delivery and therapeutic gene expression to the tumor vasculature. In addition, polymer based formulations are being developed for intramuscular administration. The purpose is to convert the transfected muscle cells into bioreactors for expression and secretion of therapeutic proteins into the blood stream. His present research program is focused on applying these technologies to the treatment of cancer, with emphasis being placed upon brain cancer.

Dr. Hans Schreier received his dipl. pharm. ETH degree in 1976 and his Dr. sc. nat. degree in 1981 from the Swiss Federal Institute of Technology (ETH) Zurich, Switzerland, followed by postdoctoral training at UCSF and a Senior Scientist position at Liposome Technology, Inc., Menlo Park, CA. In 1986 he joined the faculty at the University of Florida College of Pharmacy, followed by an appointment at the Center for Lung Research at Vanderbilt University School of Medicine, Nashville, TN. In 1990 he founded the biennial international “Liposome Research Days” conference at the University of Florida. The conference continues to date, held at UBC, Vancouver 2010. He was a founder and Principal Scientist of Advanced Therapies, Inc., Novato, CA, a co-founder of ARYx Therapeutics, Inc., Fremont, CA, and of MCS Micro Carrier Systems GmbH, Neuss, Germany. He has published over 70 articles, reviews and book chapters and holds several patents. He continues to serve institutions and the pharmaceutical industry as consultant.

Prof. Yusuke Tanigawara is Professor of Clinical Pharmacokinetics and Pharmacodynamics, School
of Medicine, Keio University, Tokyo, Japan. He received his Ph. D. in pharmaceutical sciences from Kyoto University in 1983. His research interests include pharmacokinetics, pharmacodynamics and dosing algorithms for personalized medicine. He has been studying clinical pharmacokinetics and pharmacodynamics for mainly oncology drugs and antimicrobial agents. His modeling and simulation studies on population pharmacokinetics and pharmacodynamics were applied to new drug development as well as rational use for patient care. Recently, he also investigates pharmacogenomics as a factor causing individual variation in drug response, and new biomarker development by means of proteomics and metabolomics techniques. He is distinguished as one of the “ISI Highly Cited Researchers.”

Markus Veit, PhD
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Dr. Veit received his PhD from Julius Maximilians University, Würzburg Germany in 1990. In 1998 he received the Egon-Stahl-Price award from the International Society of Medicinal Plant Research. His academic research interests included bioanalytical methods for active ingredients in herbal medicinal products, quality of herbal medicinal products, pharmacokinetics and bioavailability of plant phenolics, pharmacodynamics of plant phenolics, and the efficacy of herbal medicinal products. Dr. Veit published more than 50 peer reviewed publications. In 1999 Dr. Veit left his full position at University of Würzburg, Germany and started a career outside academia, but he still teaches at the School of Pharmacy, University of Frankfurt, at the Humboldt University, Berlin. Today Dr. Veit is CEO of two Companies offering regulatory and analytical services for the Pharmaceutical Industry (HWI ANALYTIK and i.DRAS). 2011 he additionally founded ALPHATOPICS, a company offering training and consultancy services. He is a member of the German Pharmacopeia Expert committee Pharmaceutical Chemistry. Since 1997 Dr. Veit organized, chaired and contributed at more than 150 symposia and seminars covering his main interests and expertise: Drug regulatory affairs, quality of pharmaceuticals and medical devices, pharmaceutical development, bioanalytical method development and validation.

Yaning Wang, PhD
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Dr. Yaning Wang is currently the Associate Director for Science in the Division of Pharmacometrics in the Office of Clinical Pharmacology at FDA. Before joining FDA, Dr. Wang received his Ph.D. in Pharmaceutics and master’s degree in Statistics from the University of Florida from 1999 to 2003. He also obtained a master’s degree in Biochemistry (1999) and a bachelor’s degree in Pharmacy (1996) from Peking University in China. Dr. Wang joined FDA as a clinical pharmacology and pharmacometrics reviewer in 2003, conducting reviews in the therapeutic areas of anti-infectives, special pathogen, transplant, antivirals, cardiovascular and renal products, oncology, neurology, psychiatrics, metabolism and endocrinology, pulmonary
and allergy. In 2005, he became a senior reviewer. In 2007, he became the pharmacometrics team leader responsible for the therapeutic areas of cardiovascular and renal products, oncology, medical imaging, hematology, gastroenterology, metabolism and endocrinology, pulmonary and allergy, special pathogen, and transplant. In 2009, his therapeutic responsibility changed to neurology, psychiatrics, pulmonary and allergy, analgesics, anesthetics, and rheumatology due to team realignment. In 2010, in addition to his team leader responsibility, Dr. Wang was appointed as the Associated Director for Science to oversee the scientific aspects of reviews, research projects, and policy development within the Division of Pharmacometrics to ensure high quality science. In 2012, he took on the team leader’s responsibility for antivirals, anti-infectives and ophthalmology, special pathogens and transplant, cardiovascular and renal products, dermatology and dental, and reproductive and urologic products. Dr. Wang received numerous awards at FDA, including Award of Merit, the most prestigious honor awarded at FDA. Dr. Wang is an Adjunct Professor in the Department of Pharmaceutics at the University of Florida and an invited lecturer in the College of Engineering and College of Pharmacy at the University of Michigan. Dr. Wang also serves as a committee member for two Ph.D. candidates from the University of Florida and the University of Minnesota. He has published 30 papers and given more than 60 presentations at various national and international meetings. Dr. Wang serves as the FDA representative on the Scientific Advisory Board for Drug Disease Model Resources (DDMoRe) consortium and on the Editorial Advisory Board for the Journal of Pharmacokinetics and Pharmacodynamics.

**Russell S. Weiner, PhD**  
**Bristol Myers Squibb**  
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Dr. Weiner is currently Group Director of Clinical Biomarker and Bioanalytical Sciences at Bristol-Myers Squibb. He received his Ph.D. in Biochemistry from Albany Medical College and in 1993 joined the Department of Bioanalytical Research at Bristol-Myers Squibb, where he was responsible for regulated bioanalysis in support of GLP and clinical studies. In 2002, Russ and joined the Department of Clinical Discovery-Immunology, where he was responsible for transitioning compounds from discovery through Phase II clinical trials. While in this role Russ Chaired the Immunology-Early Clinical Research Team, successfully submitted eight INDs to the FDA and conducted over a dozen Phase I/II clinical trials. In 2005, Russ become Director of the Clinical Biomarker Development group combining the technologies of Immunochemistry, LC/MS, Molecular Biology, Molecular Pathology and Flow Cytometry along with clinical trial operations and pharmacogenetic sample banking. In March 2007, Russ broadened his responsibilities to also include the Biologics Bioanalytical Sciences group responsible for PK and Immunogenicity assay development, validation and sample analysis. Russ is an active member of AAPS where he currently serves as Chair of the 2009 Annual Meeting, Past-Chair of the Biotechnology Section and AAPS Visiting Scientist. Through Russ’ involvement in AAPS he has co-chaired several workshops that focused biomarkers and regulated bioanalysis of both large and small molecules. The results of these workshops are white papers that provide best practice guidelines for areas currently lacking official FDA guidance.

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Wolfgang Wuttke, MD, Professor of Endocrinology, University Medical Center Goettingen. Research Interests: Search for compounds in plants with endocrine activities. In particular, plant extracts and thereof purified substances are investigated which can alleviate climacteric complaints, the development of the metabolic syndrome, osteoporosis, arthrosis and sarcopenia. Research is performed with cell biological and animal experimental models utilizing quantitative computer tomography, quantitative RT-PCR, quantitative histomorphometry including immune-histo-chemistry and quantification of proteins or hormones in organ extracts or in the blood. With these tools mechanisms of actions of plant extracts and thereof purified substances are determined in cell biological experiments or in rodents (rats and gene targeted mice).

Ping Zhao, PhD

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Ping Zhao is currently a senior clinical pharmacologist in Immediate Office of the Office of Clinical Pharmacology, Office of Translational Sciences, Food and Drug Administration (FDA). He obtained his BS in Pharmacy from Beijing Medical University in China in 1994, and his PhD in Pharmaceutics from University of Washington, Seattle, WA in 2002. Since then, Ping worked as DMPK scientist in several pharmaceutical companies. In June 2008, Ping joined the Office of Clinical Pharmacology at FDA. His primary responsibilities are to assess the effect of multiple patient factors (intrinsic and extrinsic) using mechanistic modeling and simulation and to evaluate the application of physiologically-based pharmacokinetic (PBPK) tools to support regulatory reviews. He contributes the update of several “Guidance for industry” documents (e.g., drug-drug interaction, pediatrics, renal impairment, pregnancy). Ping serves as an ad hoc clinical pharmacology reviewer for numerous INDs and NDAs, provides consultation to fellow reviewers on drug metabolism, drug-drug interaction and the application of PBPK, and organizes/provides training on the use of PBPK tools. He manages several FDA research projects including Critical Path, and mentors several research fellows.

Governance

Decisions concerning curricular revision and student admissions are made after the department faculty has met to discuss such matters and each faculty member has voted on that particular issue.

Recruitment of Students

The PhD program of the Department of Pharmaceutics is listed in the graduate catalog, and is advertised in mailings to well qualified graduates of the University of Florida and on the College
Admission Policies and Procedures

The College of Pharmacy adheres to the minimum standards set forth by the Graduate School:

- A grade point average (GPA) of at least 3.0 (4-point system);
- Three (3) letters of recommendation.

In addition to the above requirements, foreign applicants must have:

- All international students seeking admission to the Graduate School must submit satisfactory scores on the GRE General Test

Although a formal interview is not required at this time, applicants are encouraged to visit the department/center prior to or during the application process.

Financial Assistance

It is the general policy of the Department of Pharmaceutics that all students accepted to pursue graduate studies receive support in the form of a teaching or a research assistantship, or show evidence of adequate support from a fellowship or other source. Currently, the minimum stipend is approximately $15,000/year.

Teaching assistantships are normally provided for a four (4) year period of time contingent upon continued funding from State sources. A student may receive support for one (1) more year if a relevant reason is presented to the departmental faculty by the major advisor, and the departmental faculty approves the request by majority vote of all the faculty. Except in extenuating circumstances, the department is not financially responsible for any student taking longer than 5 years to complete the doctoral program.

Those students assigned to teach during any given semester by the graduate studies coordinator are appointed Teaching Assistant (0.33 FTE) and are required to work 13.3 hours per week. All graduate students receiving a stipend who are not employed as teaching assistants will be designated Research Assistants or Fellows depending on the source of funds. Stipends are provided so that students may pursue research required to complete their educational programs. Students are expected to diligently pursue that research.

Prior to the beginning of each fiscal year, every graduate student will receive a statement specifying (i) total amount of stipend for that period, (ii) position to which appointed, e.g. TA, R.A., or other, (iii) starting and ending dates of appointment, (iv) assignment for that period, (v) the supervisor for that period, and (vi) other pertinent information. A copy of this document will be kept in the student's personnel file. Students will be asked to sign the form to indicate that it has been read, understood and accepted.
At the end of each fiscal year, each student will be evaluated on his/her assigned duties by the supervisor in writing. The student has the right to a written rebuttal in case he/she does not agree with the evaluation. The evaluation will also be kept in the student’s personnel file.

A faculty member may support with his/her own funds any number of graduate students in addition to the College-supported graduate students. The stipend paid by the faculty member cannot be used to supplement an existing college supported stipend.

Students are encouraged to apply for national and graduate school fellowships and awards. If a student succeeds in receiving a grant, the department or the center may supplement the student's salary with a fraction of the amount up to the current funding levels (provided the granting agency allows such an arrangement).

Decisions concerning the allocation of state stipends are made by the departmental faculty at the same time as a decision is made to admit a particular candidate.

**Selection of Discipline for Degree and Major Professor**

Students must select a major advisor by the end of their second semester of graduate school but are encouraged to do so as early as possible.

If a student desires to change the major advisor, he/she must discuss the change with the current advisor. If both parties agree to such change, the student may select a new advisor. If the parties cannot come to an agreement concerning the proposed change, then the student and the faculty member must each write a letter to the department chairperson explaining the situation. The student must specify the reason(s) for deciding to change. The advisor's letter must specify the reason(s) for the disagreement and contain an overall evaluation and appraisal of the situation. The department chairperson will evaluate the letters, discuss the situation with both individuals, and decide. If the student is permitted to change advisors, he/she will not be allowed to continue the same research project with another faculty member, except if both faculty members agree in writing to the department chairperson that the student should continue the same project under the new advisor.

The department graduate coordinator will advise the student in general policies as set forth in this document. The graduate coordinator is also responsible for general oversight of the graduate program for quality assurance of the program, assignment of teaching duties, and recruitment of graduate students.

**Supervisory Committee**

The supervisory committee is proposed by the student's major advisor in consultation with the student, nominated by the department chairperson, approved by the Dean of the College of Pharmacy, and appointed by the Dean of the Graduate School. Each committee member should
hold Graduate Faculty status with the Graduate School. The Dean of the Graduate School is an ex-officio member of all supervisory committees. The supervisory committee must be appointed no later than the second term of the doctoral program. The student is encouraged to meet with the supervisory committee as often as possible.

The supervisory committee shall consist of at least four (4) members of the Graduate Faculty. At least two (2) members must be from the Department of Pharmaceutics, and at least one (1) member other than the chairperson must be tenured faculty; at least one (1) member must be from a different educational discipline outside the College of Pharmacy. The chairperson need not be tenured, but must hold a full-time tenure track position in the Department of Pharmaceutics.

In unusual cases, the doctoral research may require the guidance of a specialist in an area of study other than that of the supervisory committee chairperson. In such cases, the department chairperson may recommend the appointment of a co-chairperson who should be on the graduate faculty.

**Duties of the Supervisory Committee**

- To provide optimal support and guidance to the student to help the student meet his/her academic goals.
- Inform the student of all regulations governing the Ph.D. degree. This does not absolve the student from the responsibility of becoming informed of these regulations.
- To meet soon after appointment with the student to consider the student's individual goals and proposed program, and evaluate the student's progress to date.
- To conduct the student's **written** qualifying examination after the student has completed all required course work. The supervisory committee should also assist in the departmental oral qualifying exam. After successful completion of the written and oral exam, the committee will discuss and approve the student's dissertation topic, and, if the student has passed the examination to the committee's satisfaction, recommend the student's admission to candidacy.
- The supervisory committee should monitor and evaluate the student's progress and give clear directions as to the final work plan leading to graduation. It is recommended that the committee meet once a year before the student advances to candidacy and every six months thereafter to review the student's research and to make suggestions for completion of research, and approve that the student is ready to write up the dissertation as soon as the major advisor and student are convinced that the research is nearing completion.
- To conduct the final oral examination in defense of the dissertation.
Curriculum
A minimum of 90 semester hours beyond the Bachelor's degree is required for the doctoral degree. All credits earned in the approved degree program count toward this minimum. Course work must be 5000 level or higher. Courses for major credit must be taken by letter grade, except for those courses listed as S/U in the catalog.

Total Credits: 90 hours
Didactic Credits: 30 hours
Research Credits: 60 hours
Each student, together with his/her committee, will construct a course program of study specifically designed to meet the student's interest including the following core courses:

<table>
<thead>
<tr>
<th>Core Courses Required for PhD Pharmaceutics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Statistics:</strong></td>
</tr>
<tr>
<td>STA 6166 (3) Statistical methods in Research 1</td>
</tr>
<tr>
<td><strong>Drug Metabolism:</strong></td>
</tr>
<tr>
<td>PHA 6427 (2) Pharmacogenomics of drug metabolism and transport</td>
</tr>
<tr>
<td><strong>Ethics:</strong></td>
</tr>
<tr>
<td>VME 6767 (1) Issue Responsible Research</td>
</tr>
<tr>
<td><strong>Grant Writing:</strong></td>
</tr>
<tr>
<td>ALS 6046 (2) Grant Writing</td>
</tr>
<tr>
<td><strong>Pharmaceutics:</strong></td>
</tr>
<tr>
<td>PHA 6416 (3) Pharmaceutical Analysis</td>
</tr>
<tr>
<td>PHA 6125(3) Advanced Pharmacokinetics</td>
</tr>
<tr>
<td>PHA 6938 (1) Seminar [Max 3]</td>
</tr>
</tbody>
</table>

| Research: | Non-Candidate |
| Candidate: | |

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Recommended Courses

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Title</th>
<th>Department</th>
<th>Offered</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHA 5172 (2)</td>
<td>Pharmaceutical Biotechnology</td>
<td>PC</td>
<td>TBD</td>
</tr>
<tr>
<td>PHA 5475</td>
<td>Synthesis of Prodrugs</td>
<td></td>
<td>TBD</td>
</tr>
<tr>
<td>PHA 6116 (3)</td>
<td>In Vivo &amp; In vitro Stability of Drugs</td>
<td>PC</td>
<td>Fall Even Years</td>
</tr>
<tr>
<td>PHA 6170C (3)</td>
<td>Product formulation</td>
<td>PC</td>
<td>Fall Odd Years</td>
</tr>
<tr>
<td>PHA 6183 (3)</td>
<td>Pharmaceutical Delivery</td>
<td>GenePC</td>
<td>Spring Odd Years</td>
</tr>
<tr>
<td>PHA 6185 (3)</td>
<td>Pharmaceutical Development</td>
<td>DrugPC</td>
<td>Spring Even Years</td>
</tr>
<tr>
<td>PHA 6449 (2)</td>
<td>Pharmacogenomics</td>
<td>PTR</td>
<td>Spring Even Years</td>
</tr>
<tr>
<td>PHA 6894 (1)</td>
<td>Introduction to Graduate Studies</td>
<td>PC</td>
<td>Spring</td>
</tr>
<tr>
<td>PHA 6896 (2)</td>
<td>Preclinical Drug Evaluation</td>
<td>PC</td>
<td>TBD</td>
</tr>
</tbody>
</table>

Students with adequate training in any of the above courses may apply for exemption from such courses, but they must have credit for a minimum of thirty (30) semester hours of approved didactic courses. The remaining course requirements can be fulfilled by completion of electives from the provided list or the graduate catalog selected in consultation with the students advisory committee. It is also essential that the student ensure that they have a basic understanding of Pharmaceutics either by taking the appropriate classes or from previous education. They should be proficient in the basic sciences at a minimum to the same degree as students in the professional program. Questions will be asked during the oral qualifying exam.
**LIST OF APPROVED GRADUATE COURSES:**

- PHA 5475 - Synthesis of Prodrugs (3 credits)
- PHA 5515 - Introduction to Pharmacology (1 credit)
- PHA 5516 - Pharmacological Basis of Therapeutics (4 credits)
- PHA 5517 - Pharmacology II (4 credits)
- PHA 6115 - Equilibria, Complexations, and Interactions of Drugs (3 credits)
- PHA 6118 - Molecular Diversity (2 credits)
- PHA 6354 - Natural Medicinal Products (3 credits)
- PHA 6417 - Pharmaceutical Analysis II (3 credits)
- PHA 6508 - Mammalian Physiology (4 credits)
- PHA 6509 - Mammalian Physiology (4 credits)
- BCH 6206 - Advanced Metabolism (3 credits)
- BCH 6740 - Advanced Physical Biochemistry (3 credits)
- BCH 7515 - Enzyme Kinetics and Mechanisms (2 credits)
- BMS 5201 - Introduction to Biochemistry and Molecular Biology (3 credits)
- BMS 5520C - Principles of Physiology (2 credits)
- BMS 6400 - Introduction to Pharmacology (5 credits)
- BMS 6402 - Autonomic and Cellular Pharmacology (2 credits)
- CAP 5506 - Programming Language Principles (3 credits)
- CAP 5635 - Artificial Intelligence Concepts (3 credits)
- CAP 6627 - Expert Systems (3 credits)
- CAP 6653 - Neural Networks for Computing (3 credits)
- CHM 4411 - Physical Chemistry (4 credits)
- CHM 5224 - Basic Principles for Organic Chemistry (3 credits)
- CHM 5235 - Organic Spectroscopy (3 credits)
- CHM 5275 - The Organic Chemistry of Polymers (2 credits)
- CHM 5305 - Chemistry of Biological Molecules (3 credits)
- CHM 5514 - Chemical Computations (2 credits)
- CHM 6154 - Chemical Separations
- CHM 6155 - Spectrochemical Methods (3 credits)
- CHM 6225 - Advanced Principles of Organic Chemistry (4 credits)
- CHM 6226 - Advanced Synthetic Organic Chemistry (3 credits)
- CHM 6211 - Chemistry of High Polymers (2 credits)
- CHM 6480 - Elements of Quantum Chemistry (3 credits)
- CHM 6520 - Chemical Physics (3 credits)
- CHM 6720 - Chemical Dynamics (3 credits) CHS 5110 - Radiochemistry (2 credits) CHS 5110L - Radiochemistry Laboratory (3 credits)
- GMS 6500 - Introduction to Pharmacology (5 credits)
- GMS 6563 - Molecular Pharmacology (3 credits)
- GMS 6735 - Neuropharmacology (3 credits)
- GMS 7593 - Principles of Drug Action (2 credits)
- GMS 7595 - Topics in Pharmacology (e.g. Principles of Drug Action, 2 credits)
- MBS 7423 - Principles of Drug Action (2 credits)
ALL GRADUATE STUDENTS should register for (a) the 1 credit Pharmaceutics Department research seminar each semester, using number PHA 6938 (Research Seminar; 1 credit; S/U option; maximum 3 credits).

- FOR NON- CANDIDATES: Graduate students who have not yet attained candidacy for the Ph.D. should register for PHA 7979 (Advanced Research; 1 to 9 credits).
- FOR CANDIDATES: Candidates for the Ph.D. degree should register for PHA 7980 (Research for Doctoral Dissertation; 1 to 15 credits).

**Qualifying Examination**
Satisfactorily passing the qualifying examination is a requirement for admission to candidacy, i.e., when the student actually becomes a candidate for the Ph.D. degree. In order to take the qualifying examination, the student must (i) have a minimum 3.00 GPA; (ii) have completed letter-grade course work; (iii) have completed all core courses; and (iv) be registered at the time the examination is taken. Exceptions (e.g., if a core course is not offered, but the student has fulfilled all other requirements and has formulated a research program) may be granted by the supervisory committee. It is expected that the qualifying exam will focus on the student’s own prepared NIH grant proposal but in addition; background information from course work and general questions of pharmaceutics may be asked of the student.

**General Guidelines**

- The format for the comprehensive examination will be a combined written/oral examination.
- The comprehensive examination should be completed between the time when all course work is completed and no later than eight months prior to scheduling of the dissertation defense. It is expected that the oral comprehensive examination will be taken by the end of the third year in the graduate program.
- The written part of the comprehensive examination committee for each student will be chaired by a faculty member in the Department of Pharmaceutics who is a member of the graduate faculty. The student’s academic advisor will be a member of the committee but may not be the committee chair. Composition of the committee will be consistent with University guidelines for dissertation committees (i.e., at least four faculty members with the majority being graduate faculty). It is anticipated that the examination committee will subsequently serve as the dissertation committee.
- The comprehensive examination committee will have a meeting prior to the comprehensive examination to discuss lines of questioning and to address core competencies (relative to each focus area). The chair of the examination committee will communicate the proceedings of this meeting to the Graduate Program Administrator. The oral part of the exam is open to the entire department.
Guidelines for Proposal Preparation

1. The topic of the research proposal must be an original research project. The topic may be the student’s proposed dissertation research. A written abstract of the research proposal, maximum of one page in length, should be examined and approved by the academic advisor and the oral comprehensive examination committee prior to preparation of the complete proposal.

2. The written proposal, maximum of 10 pages of text plus references, prepared in the format of a granting agency (e.g., NIH R03) should be distributed along with "key" references to the committee at least 14 days prior to the oral comprehensive examination.

3. The graduate student will give an oral presentation that should be succinct, yet complete (approximately 20-30 minutes), and be supported by visual aids.

4. The committee will identify questions relevant to each research focus area, which may include but not be limited to:

   - Literature evaluation skills
   - Writing skills
   - Scientific background
   - Study design
   - Utility of animal models of disease or conditions relative to the human situation
   - Analytical methods
   - Clinical measurement methods
   - Data and statistical analysis skills
   - Differentiation of clinical and statistical significance
   - Basic Sciences covered in the Professional Program (Physical Pharmacy, Biochemistry, Pharmacokinetics, Biochemistry, Pharmacology, Medicinal Chemistry and Statistics)

5. The final evaluation by the dissertation committee should be communicated to the student and the graduate academic affairs committee utilizing the following scale:

   a. Pass - With written feedback on strengths and weaknesses

   b. Remedial work needed:
      - Specific needs for additional learning experiences (e.g., scientific area, statistics, writing, etc.) may be identified.
      - Remedial work may include a minor rewrite of the proposal or a major rewrite and re-defense of the proposal.
      - Remedial work must be completed within six months from the time of examination.

   c. Fail - A student who fails the qualifying examination will be terminated from the Ph.D. program.
Oral Comprehensive Examination Guidelines for Proposal Preparation Procedures

Oral comprehensive exam proposals are to be submitted on NIH grant application form PHS 398 continuation pages and prepared according to the directions in the application packet, with the exceptions noted below. Forms and instructions are available on the internet at:

http://grants.nih.gov/grants/funding/phs398/phs398.html

Research Plan

Do not exceed a total of ten pages for the following parts (a-d): Specific Aims, Background and Significance, Progress Report/Preliminary Studies, and Experimental Design and Methods. Tables and figures are included in the ten page limitation. Applications that exceed the page limitation or PHS requirements for type size and margins (Refer to PHS 398 application for details) will be returned for revision. The ten page limitation does not include parts e through i. (Human Subjects, Vertebrate Animals, or Literature Cited).

(a) - Specific Aims – (1 page). List the broad, long-term objectives and what the specific research proposed in this application is intended to accomplish, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, or develop new technology.

(b) - Background and Significance – (2-3 pages). Briefly sketch the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. Concisely state the importance and healthcare relevance of the research described in this application by relating the specific aims to the broad, long-term objectives.

(c) - Preliminary Studies/Progress Report – (2-3 pages). Use this section to provide an account of the students’/academic advisors’ preliminary studies pertinent to the application information that will also help to establish the feasibility of the proposed project.

(d) - Research Design and Methods – (4-5 pages). Describe the research design and the procedures to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted. Describe any new methodology and its advantage over existing methodologies. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. As part of this section, provide a tentative sequence or timetable for the project.

See http://grants.nih.gov/grants/funding/phs398/section_1.html#8_research for complete instructions regarding sections (e) and (f).

(e) – Human Subjects Research

(f) – Vertebrate Animals
Literature Cited. (No page limit). List all references. Each reference must include the title, names of all authors, book or journal, volume number, page numbers, and year of publication. The references should be limited to relevant and current literature. While there is not a page limitation, it is important to be concise and select only those literature references pertinent to the proposed research.

**Final Examination**

After submission of the original copy of the dissertation to the Graduate School (see below) and completion of all other work for the degree, and the appropriate dates and time intervals will follow the guidelines set forth by the University of Florida Graduate School, as detailed in the Graduate Catalog.

An announcement of the scheduled examination must be submitted in writing to the Dean of the Graduate School by the chairperson of the supervisory committee at least ten (10) working days prior to the scheduled date through GIMS. An announcement of the examination is sent at least one (1) week prior to the date of examination to faculty members in the College of Pharmacy, inviting them to attend.

At least four (4) faculty members, including all members of the supervisory committee, must be present at the final oral portion of the final examination. The four (4) faculty members must be Graduate Faculty members. Only the official members of the supervisory committee sign the dissertation signature pages.

Assuming the candidate is successful, the Final Examination Report shall be signed by all faculty members attending the examination. The dissertation, original and copies, are to be signed by the official members of the supervisory committee and by the Dean of the College of Pharmacy. Confirmation of passing the Final Examination is done online through GIMS.

Every candidate for a doctoral degree is required to prepare and present a dissertation that shows independent investigation, and is acceptable in form and content to the supervisory committee and to the Graduate School. Since all doctoral dissertations will be published it is necessary that the work be of publishable quality and that it be in a form for publication. A draft copy of the dissertation must be given to the supervisory committee members at least one month prior to the defense. This allows time for any major changes to be made. A final copy of the dissertation should be circulated to the committee at least one week before the final defense.

All copies of the dissertation, except the original copy and the Health Center copy, must be provided as a hard bound copy by the student. The original copy and the second copy of the dissertation must be presented to the Dean of the Graduate School on or before the date specified in the University Calendar.
Specific Requirements for the Master of Science in Pharmacy Degree

Students will not generally be admitted for studies toward an M.S. in this specialization. However, a student admitted to the doctoral program may be allowed to graduate with a Masters in Pharmacy subject to approval by the students supervisory committee. The M.S. in Pharmaceutical Sciences is described in the graduate catalog and requires the completion of a thesis or dissertation.

Graduate Student Classification:
Students pursuing the Master of Science in Pharmacy degree are classified 7PH.

Degree Requirements:
Unless otherwise specified, for a master's degree, the student must complete a minimum of 30 credits including no fewer than 24 hours of regular course work and up to 6 credits in thesis research as a graduate student at the University of Florida. No more than six semester hours of course work earned with a grade A, B+ or B may be transferred from institutions approved by the Dean of the Graduate School.

Major:
All course work for a master’s degree must be in courses open only for graduate credit (5000 and above).

Credits and Grades:
The 24 credits of minimum regular course work recommended by the supervisory committee and the supervisory chair, must be taken by letter grade. The student must have a minimum 3.00 GPA for all course work attempted for the degree, and a minimum 3.00 GPA for course work in the major. The course program will be determined by the thesis committee.

Thesis:
The candidate is required to prepare and present a thesis acceptable to his/her supervisory committee and the Graduate School. He/she should consult the Graduate School for instructions concerning the forms of the thesis, binding, and the date when the original copy, accompanied by three (3) copies of abstracts are to be submitted to the Graduate School.

Supervisory Committee for the Master of Science in Pharmacy:
At least three members selected from the Graduate Faculty must be on the supervisory committee. These members are recommended by the student's supervisory chair, approved by the College Dean for Research and Graduate Studies, and appointed by the Graduate School. The Dean of the Graduate School is an ex-officio member of all supervisory committees. If a minor is designated, it should be represented by one member of the committee who is on the Graduate Faculty. The committee should be appointed as soon as possible, and no later than the end of the second semester or 24 credits, whichever comes first.
Only members of the Graduate Faculty may be members of the supervisory committee. Names of courtesy faculty, regular faculty, and others not on the Graduate Faculty should not appear on the student's official supervisory committee.

At least three faculty members must be present at the student's final examination. Only members of the official supervisory committee are required to sign the thesis and the report of the final examination.

**Residency Requirement:**
There is no residency requirement for the master's degree.

**Admission to Candidacy:**
Admission to candidacy is no longer required for students pursuing master's degrees.

**Final Examination:**
A written announcement of the examination is sent to the Graduate School Dean and all faculty in the College of Pharmacy. When the student's course work is completed, or practically so, and the thesis is in final form, the student's supervisory committee is required to examine him/her in writing or orally on his/her thesis and the subject matter of the courses taken for the degree. The form Report on Thesis/Dissertation and Final Examination should be completed and signed by the official members of the committee, and then by the department chair/center director and the College Dean. This form should then be submitted to the Graduate School via GIMS.

The Final Examination Record should be submitted to the Graduate School with the thesis by the date specified in the University Calendar. The final examination may not be held any earlier than six months before the degree is to be conferred.

**Time Limitation for Completion of The Master of Science in Pharmacy:**
All work counted toward the M.S.P. degree must be completed during the seven years immediately preceding the date on which the degree is to be awarded.

**Correspondence and Extension Work:**
No courses may be taken for graduate credit by correspondence. No extension courses may be used for graduate credit.