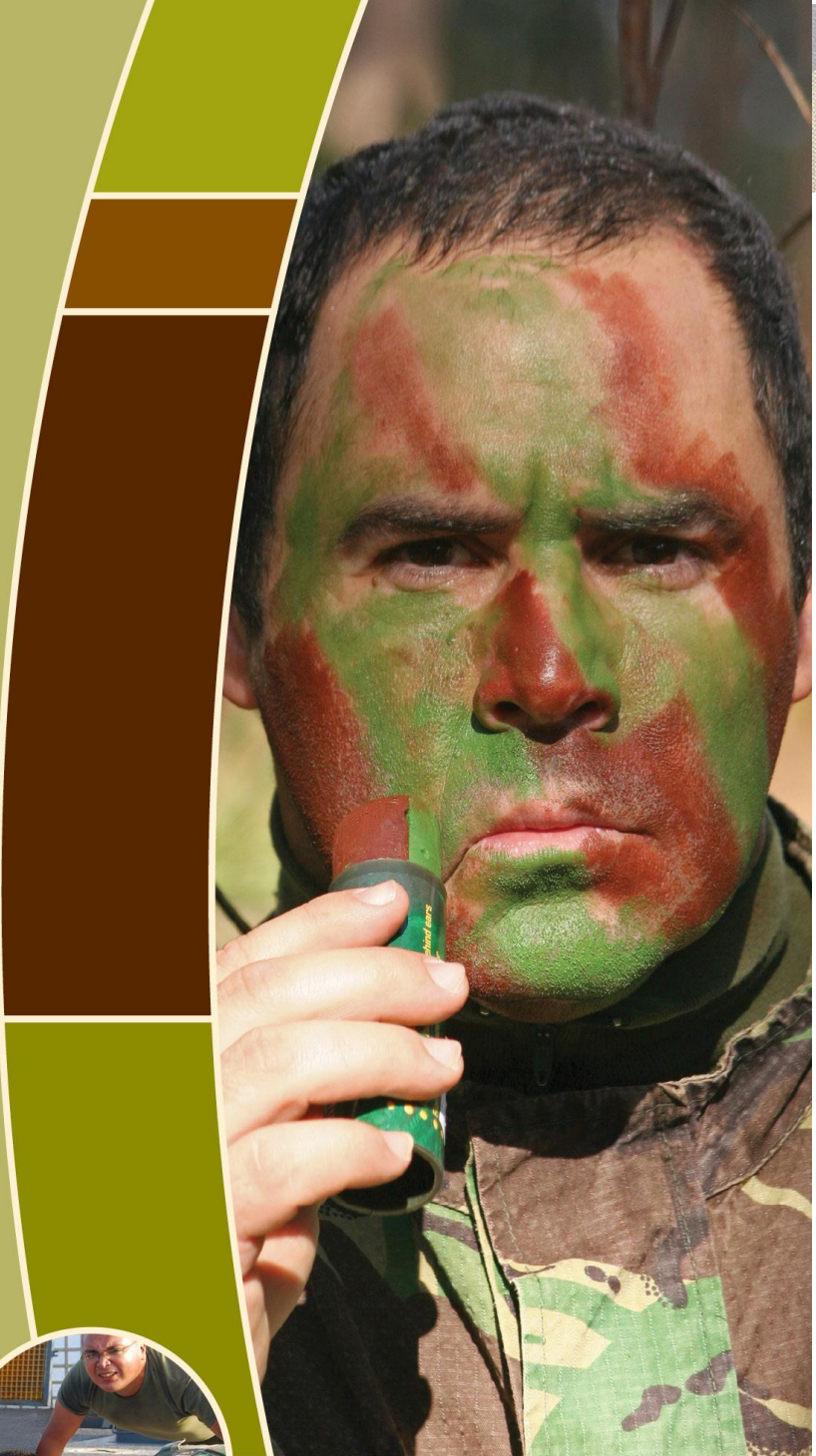


Drug Development Boot Camp

An Intensive Two Day Course for Biotech, Pharma Executives, and Harvard University Investigators

November 14-15, 2012
The Harvard Club
Boston, MA



HARVARD UNIVERSITY
Office of Technology Development



Overview

The process of drug development is becoming more and more complex. At the same time, it is becoming more and more expensive. Only 11% of drugs will make it through the drug development and registration processes to commercialization. Those involved with the process of developing new therapeutics (drugs, devices, combination products and diagnostics) must understand the process and be able to navigate it with great skill because failure is incredibly expensive. Those working in drug development must “get it right first time”. Drug development skills are difficult to acquire.

The Drug Development Boot Camp will allow simulations of the drug development process so that hands-on experience can be gained. A mixture of large pharma, small pharma and expert panel members will ensure panel discussions are relevant, responsive and applicable to everyday situations that participants face. This program will consider the process from drug discovery (designation of a development lead) to registration. The major aspects of development will be considered in a unique, systematic and coordinated way.

Who should attend?

- CEOs, CFOs, COOs of biotech companies
- Executives involved with the drug development process
- Small and virtual company executives
- Large pharma professionals involved with drug development
- Regulatory affairs professionals, clinical research professionals, senior research scientists, toxicologists
- Clinical investigators who would like to gain an understanding of drug development, or improve their understanding of the drug development process
- Senior scientists wishing to transition into drug development

Why should my company be represented at the Drug Development Boot Camp?

- Are you an executive with many years of experience developing drugs?
- Are you working on novel drugs with questions that the project team is having difficulty answering?
- Do you have knowledge gaps in the drug development area?
- Do you want to understand what you would need to do to get a drug registered or partnered?
- Do you wonder why you are having challenges getting your company's drugs partnered?

What can I expect from this event?

- You will learn about drug development in a hands-on manner
- You will learn how to move hypothetical drugs through the process of drug development in a step-wise manner
- You will hear from large pharma and successful small and mid-size companies about the lessons that they have learned in developing their drugs
- There will be many opportunities for networking and working through challenges with peers

What benefit can I expect from participating in this event?

- You will leave with knowledge and experience that you can apply to your company's drug development challenges.
- From interacting with large pharma experts, you will gain invaluable insights into what you need to do to make your program attractive to them for exit purposes

Outline Agenda

Day 1 Start at 7:00 am EST	Day 2 Start at 7 am EST	Special Features
<p>COMMERCIAL SESSION Drug Discovery to Product Candidate The criteria for selecting the lead candidate will be explored.</p>	<p>CHEMISTRY MANUFACTURING CONTROLS (CMC) The inter-relationship of CMC to safety and efficacy will be explored in a lot of detail. The CMC session will also cover Process analytical technologies (PAT) and manufacturing scale-up.</p>	<p>This two day intensive Boot Camp will be interspersed with workshops, breakout sessions, case study analyses and puzzles.</p> <p>The hands-on approach will enable those with experience in drug development to gain an understanding of areas that they are as yet unfamiliar with.</p> <p>Those with 5 years or less experience in drug development will leave with an understanding of how to effectively move a compound through the drug development process. Those with 5 to 10 years of experience will deepen their knowledge of the drug development process and will be able to apply their knowledge to complex drug development situations in carefully constructed Workshops.</p> <p>The Drug Development Boot Camp is extremely interactive.</p> <p>It is taught by expert drug developers. The Faculty are experts in their fields..</p> <p>The course content has been put together very carefully to achieve the goals of teaching about the Drug Development process in a lot of detail. Because of the workshops and case studies that you will work on, the learning process is fun and hands-on.</p> <p>Information is imparted by the Faculty, but the understanding of this material is reinforced and tested throughout the Boot Camp. Participants are able to work on the material provided with other participants using case studies.</p> <p><i>A good level of understanding of the drug development process is presumed. Background reading should be undertaken before</i></p>
<p>REGULATORY AFFAIRS The Target Product Profile and Development of the Regulatory Strategy</p> <p>The critical importance of the Target Product Profile and the process for defining it will be presented. The interfaces of marketing, clinical and reimbursement will be explored.</p> <p>The importance of developing a global regulatory strategy will be considered. A method for developing the global regulatory strategy will be presented.</p>	<p>The CLINICAL PHASE The four phases of clinical development, the goals of each, and the potential issues to be managed will be identified and explored in detail.</p> <p>Clinical strategy and operations will be covered in a lot of detail.</p> <p>A clinical Workshop featuring a real case study will be presented.</p>	
<p>PRECLINICAL DEVELOPMENT Preclinical Efficacy</p> <p>Different methods for demonstrating proof of concept during the preclinical phase will be presented and considered in detail.</p> <p>Scale up of the data obtained to preclinical toxicology studies will be considered.</p>	<p>WORKSHOPS - AFTERNOON OF DAY 2</p> <p>Participants will be divided into project teams according to their levels of previous drug development experience, skills, and their objectives stated on a questionnaire.</p> <p>The Project Teams will work on drug development case studies.</p> <p>Each project team will report back to the whole group regarding how their case studies.</p> <p>The Faculty will present the responses. This is a time to consolidate all that has been learnt during the Boot Camp.</p>	
<p>PRECLINICAL TOXICOLOGY Clinical Development and the inter-relationship with toxicological evaluation up to</p>	<p>MOVING INTO THE REGISTRATION PHASE Participants will gain an understanding of how to move a compound from drug discovery</p>	

Day 1 Start at 7:00 am EST	Day 2 Start at 7 am EST	Special Features
registration The interface of GLP toxicology studies, CMC and clinical will be considered in detail.	towards the goal of registration in the major countries as well as internationally. Electronic submissions and how to manage the process will be presented.	<i>attending this Boot Camp to ensure that you will gain the maximum from the Boot Camp. Dr. Speid can recommend books for this purpose.</i>
Reception and Networking This is a time to relax after a day of learning and network with your colleagues, make new connections and exchange experiences that were learnt during Day 1. Day 1 will finish at about 8 pm EST at the end of the Reception. Background reading will be provided for overnight reading, in preparation for Day 2.	PANEL Q&A AND DISCUSSION Your opportunity to ask remaining questions, discuss your individual project challenges, etc. Experts will take questions from the participants. These questions may be questions arising from the course or questions from their own drug development situations.	Certificates of Attendance for continuing education purposes will be presented to all who complete the complete two day intensive course. Day 2 will end at about 6:30 pm EST. Certificates can only be provided to those who remain to the end of the Boot Camp.

Speakers and Panel Members: Faculty

Madeline Baer, Ph.D., J.D., Counsel, Vinson & Elkins LLP Attorneys at Law

Areas to be covered: Intellectual Property Matters

Madeline Baer is a Counsel in the New York office of Vinson & Elkins LLP. She has represented global, midsize and start-up biotechnology and pharmaceutical companies in patent litigations, opinions, patent prosecution, and due diligence for strategic licenses, acquisitions, and public offerings and global strategic patent counseling. Dr. Baer obtained her Ph.D. in Molecular Biophysics and Biochemistry from Yale University and carried out research for many years in the area of RNA processing in the laboratory of Nobel Laureate, Dr. Sidney Altman. Dr. Baer's research contributed to the work for which Dr. Altman received the Nobel Prize. Dr. Baer is an author of peer-reviewed scientific research articles, as well as articles describing and analyzing aspects of patent law, including Markman Hearings, willful patent infringement, licensing and, most recently, post-prosecution inequitable conduct.

Akintunde (Tunde) Bello, Ph.D., Senior Director and Clinical Pharmacology Group Lead, Pfizer

Areas to be covered: Strategic Clinical (Research and Development) Phase 1 to Phase 4

Akintunde (Tunde) Bello is a Clinical Pharmacologist/Pharmacokineticist with more than 20 years of pharmaceutical industry experience gained at Pfizer, Bristol Myers Squibb (BMS) and Rhone Poulenc Rorer (RPR). Tunde has a bachelor's degree in biomedical sciences from the University of Portsmouth, UK; a masters in analytical sciences and Instrumentation from the University of Manchester Institute of Science and Technology, UK; and a PhD in Pharmaceutical Sciences (inhaled drug delivery) from King's College University of London, UK. Tunde is currently a Senior Director and Clinical Pharmacology Group Lead for a number of late stage oncology programs at Pfizer. During his career, Tunde has held leadership positions in the discovery, development and post approval research settings. He has extensive experience, spanning multiple therapeutic areas (infectious disease, oncology, CNS, inflammation, cardiovascular, and metabolic disease), in the fields of clinical pharmacology, pharmacokinetics, PK/PD, ADMET, drug metabolism, population PK, and pharmacogenetics. Prior to his current role, Tunde was a team leader in the post approval clinical pharmacology group at Pfizer, providing support (i.e., phase 4 studies, product enhancement activities, and regulatory interactions) for Pfizer drugs marketed in the Pain, inflammation and oncology therapeutic areas. During his tenure at BMS, Tunde co-led an exploratory development team responsible for the design, conduct, and reporting of more than 30 Phase I studies in support of an anti-bacterial development program. He also led on an exploratory development team responsible for the FIM to POC activities for an antifungal agent. Tunde has been involved in many regulatory interactions in support of drug development and has had active involvement in the preparation of nonclinical PK, biopharmaceutics and clinical pharmacology documents for international filings (ICH Common Technical Document format). At RPR, Tunde was a Team Leader in the Department of Discovery Drug Disposition involved in the conduct of preclinical ADMET studies for candidate compounds across multiple therapeutic areas. He also had responsibility for the development and validation of the supporting bioanalytical assays (LCMS/MS, HPLC, Liquid Scintigraphy, and various immuno assays).

Scott Boley, Ph.D., DABT., Senior Director of General Toxicology and Infusion Toxicology, MPI Research

Areas to be covered: Preclinical Development and Toxicology

Scott E. Boley, Ph.D., DABT, joined MPI Research in August 2005 as a study director in general toxicology. He received his doctorate in biochemistry and environmental toxicology from Michigan State University, where his research focused on the malignant transformation of human cells using tissue culture. His postdoctoral work, conducted over three years at CIIT Centers for Health Research (Research Triangle Park, North Carolina), involved the use of transgenic mice and molecular biology to examine tumors induced in these mice for characteristics common to human tumor formation. He then went to Eli Lilly and Company as a research scientist in nonclinical safety assessment, where he developed the nonclinical strategy for novel oncological and neurological compounds. In addition to designing and managing investigational, screening, and animal studies required for regulatory submission, he authored the toxicology sections for INDs and for clinical investigator brochures. He now serves as Senior Director of General Toxicology and Infusion Toxicology at MPI Research.

Philip Dehazya, Ph.D., Program Director, Oncology Business Unit, Aptiv Solutions

Areas to be covered: Clinical Trial Operations

Phil Dehazya currently supports Averion's business development, training and operational activity in Oncology as a member of the Oncology Business Unit. Previously in Averion's Clinical Operations Unit as Director of Clinical Research, Phil's functions included line project management for oncology studies in a variety of indications and therapeutic classes, including leukemia (AML, CTCL), solid tumors (brain, sarcoma, CRC, H&N), radiopharmaceuticals and medical devices related to oncology. He has contributed to the planning and implementation of many first-in-human trials. After Phil obtained his Ph.D. in Microbiology at UMDNJ, his post doctoral training was in tumor virology, DNA repair and chemical carcinogenesis at UC Berkeley and at the Fels Research Institute in Philadelphia. He migrated to the pharmaceutical and biotechnology industries to pursue pre-clinical research in infectious diseases, growth factors, vaccine platforms, tissue engineering, drug delivery, gene therapy and biomaterials prior to entering clinical research. He is a co-inventor and co-author on several patents and patent applications, and peer-review referee of scientific articles.

Farkad Ezzet, M.Sc., Ph.D., Senior Consultant, Strategic Consulting Services, Pharsight, a Certara Company

Areas to be covered: Modeling and Simulation and its application in Drug Development

Pharsight is a provider of software products, strategic consulting services, and reporting and analysis services to pharmaceuticals and biotechnology companies, since 2003. Dr. Ezzet was previously Head of Pharmacometrics, Drug Metabolism and Pharmacokinetics, Schering-Plough Research Institute, Kenilworth, NJ, since joining in 1999. From 1989 to 1999, he served as a Senior Statistician in the area of Modeling and Simulation at former Ciba-Geigy and Now Novartis Pharmaceuticals, Basel, Switzerland. Dr Ezzet completed research fellowships developing methodologies and software in the area of mixed-effects modeling at the University of Reading, UK and University of Lancaster, UK. He received his MS.c in Statistics from Brunel Universities, UK and his PH. D in Statistics from the University of Nottingham, UK. To date, Dr. Ezzet has authored or co-authored more than 75 manuscripts and scientific communications related to drug development.

Paul Gallagher, MBA, President, Compass Strategic Consulting, Inc.

Areas to be covered: Reimbursement Strategies, Market Access Strategies

Paul has a 35-year career in healthcare that is characterized by its breadth and extensive experience in the development and launch of innovations. During 16 years at Ciba-Geigy, Merrell Dow, and Wyeth-Ayerst, Paul held positions of increasing responsibilities in marketing research, product management, sales management and executive marketing management. From 1984 to 1988, he was Vice President of Global Marketing for Ayerst International. He has been the general manager/president of two companies in marketing communications: Medi-Promotions (U.S) and Physicians News Network. In 1994 Paul Gallagher founded Compass Strategic Consulting, Inc. While Compass provides a full range of marketing and business development services to healthcare companies with innovative technology and services, it is increasingly focused on meeting the significant demand for pricing and reimbursement assessments and strategies. Paul holds a BA in economics from Columbia University and an MBA in marketing from George Washington University. He is a member of PMRG, SCIP and Chair of the CT Chapter of LES (Licensing Executives Society). Paul has over 30-years experience within and as an advisor to major pharmaceutical companies on commercial development of in-line and pipeline products and opportunities

Thaddeus Grasela, Pharm.D., Ph.D., Cognigen Corporation

Areas to be covered: Pharmacokinetics

Thaddeus (Ted) Grasela, Pharm D., Ph.D. is President and CEO of Cognigen Corporation in Buffalo, New York, and a Fellow of the American Association of Pharmaceutical Scientists. Dr. Grasela pioneered the use of population pharmacokinetic and pharmacodynamic analyses over the past 20 years and is leading current efforts to establish model-based drug development strategies. Dr. Grasela is an Adjunct Professor in the Department of Pharmaceutical Sciences and a Senior Fellow in Entrepreneurship in the School of Management at the State University of New York at Buffalo. From 1989 to 1995, he served on the faculty of the School of Pharmacy at the University at Buffalo, where he was Associate Professor of Pharmacy, Chairman of the Department, and Director of the Center for Pharmacoepidemiology. He received his PharmD in 1979 from the Philadelphia College of Pharmacy and Science and his doctorate in Epidemiology from the University at Buffalo in 1999. Dr. Grasela is a member of the American Society for Clinical Pharmacology and Therapeutics and the American College of Clinical Pharmacology. He is the author or co-author of more than 80 peer-reviewed publications dealing with the application of pharmacometric modeling and simulations in all phases of the Pharma lifecycle from preclinical research to clinical development and commercialization.

Carlos R. Langezaal, Ph.D., Director Global Regulatory Affairs, Neuroscience Creation Unit, Eisai Inc.

Areas to be covered: Regulatory Affairs

Carlos R. Langezaal, Ph.D., Director, Global Regulatory Affairs, is currently involved with development projects in the Neuroscience Product Creation Unit at Eisai. Previously, he worked at Sanofi-Aventis, J&J PRD, Schering-Plough, Core Technologies, Eli Lilly and Baxter in various therapeutic areas, including oncology, allergy, respiratory and internal medicine. He has more than 15 years experience in regulatory affairs, having worked in the device, device/drug combination products, CMC and Clinical/non-Clinical development areas primarily with a global focus. In addition, he is an active volunteer in The Organisation for Professionals in Regulatory Affairs (TOPRA), having fulfilled the position of North America Regional Development Director from 2006 through 2010 and was as such a member of the Board of Directors.

Tom J. Parry, Ph.D., Senior Director of Pharmacology and Safety, Acorda Therapeutics

Areas to be covered: Preclinical Development and Toxicology, Case Studies

Tom J. Parry, Ph.D. joined Acorda Therapeutics in 2009 where he is now Senior Director of Pharmacology and Safety, supporting nonclinical drug development. Dr. Parry served various nonclinical pharmacology/toxicology scientific roles in multiple biotechnology companies including Ribozyme Pharmaceuticals (aka Sirna Therapeutics acquired by Merck) and Human Genome Sciences, where he helped file a number of IND's and supported development. Just prior to joining Acorda Therapeutics, Dr. Parry served as a Principal Scientist at Johnson and Johnson where he worked on multiple products including drug-eluting stents as well as cardiovascular and metabolic disease drugs. Over his 17 year biopharmaceutical career, Dr. Parry has obtained multiple research grants, patents and has authored/co-authored numerous peer-reviewed publications. In addition to his biopharmaceutical company roles, Dr. Parry serves as an adjunct faculty member at Temple University School of Medicine and School of Pharmacy where he teaches a graduate course in Pharmaceutical Biotechnology. Dr. Parry received a B.S. in Chemistry from Moravian College, a Ph.D. in Pharmacology from Temple University and was a post-doctoral fellow in Pharmacology/Psychiatry at the University of Pennsylvania. Dr. Parry also serves on the Executive Committee and was Secretary/Treasurer of the Division of Drug Discovery, Development and Regulatory Affairs of ASPET.

John J. Piwinski, Ph.D., JJPiwinski Pharma Consulting, LLC

Areas to be covered: Chemistry/Medicinal Chemistry/Co-chair of the Day 2 Workshop Session

John J. Piwinski has extensive expertise in small molecule drug discovery with over 30 years of experience in medicinal chemistry. During his career, he oversaw discovery programs in chemistry from project initiation to delivery of candidates for clinical development. He received his B.S. degree in Chemistry and Biochemistry from the State University of New York at Stony Brook in 1976 and his Ph.D. in Organic Chemistry from Yale University in 1980. He then joined Revlon Health Care as a Senior Scientist working in the cardiovascular diseases area. In 1983 he moved to Schering-Plough where he worked in the respiratory diseases group. At Schering he held positions of increasing responsibility and eventually oversaw Chemical Research as Vice President from 1999 to 2003 and Group Vice President from 2004 to 2008. In this position he was responsible for overseeing drug discovery in chemistry in Kenilworth, New Jersey in the areas of respiratory, inflammation, cardiovascular, CNS, oncology and infectious diseases. In 2008 he became the Site Head and Group Vice President of Schering-Plough's Cambridge, Massachusetts site. Research at the site focused on medicinal chemistry, affinity-based screening and optimization, bioNMR, protein science and biologics. Merck acquired Schering-Plough in 2009 and continued to operate the Cambridge site until the end of 2010. He is currently President of JJPiwinski Pharma Consulting, LLC in Lebanon, New Jersey and consults in the areas of medicinal chemistry and drug discovery, including small molecule lead discovery and optimization. He has presented numerous talks at scientific meetings and has approximately 130 published research papers, abstracts and approved U.S. patents. He has been a member of the American Chemical Society since 1975 and serves as a member for the Institute of Chemical Biology & Drug Discovery Advisory Board at Stony Brook University.

John Roberts, Ph.D., VP Pharmaceuticals & Strategy at Sirtris, a GSK Company

Areas to be covered: Chemistry Manufacturing Controls

John serves as head of the Pharmaceuticals Research department at Sirtris where he is accountable for CMC (process chemistry, formulation, regulatory, and clinical supply), DMPK (discovery and development), and bioinformatics. He has 20 years of experience in the pharmaceutical industry. Over the past three years, his organization has supported progression of three new chemical entities into 15 clinical trials. During his previous 10 years at GSK, he contributed to the development effort on 20 projects, each having cross-functional teams with representation from Clinical, Toxicology, DMPK, Regulatory, and Commercial. John has reviewed CMC documentation from numerous small companies through his involvement with due diligence and alliance partnerships at GSK. He has also contributed to multiple regulatory submissions, both as author and reviewer. Before joining GSK, John worked for three years in Chemical Development at Eisai Research Institute where his principal focus was on developing controlled processes to produce particularly challenging molecular targets. He also worked for five years at Procept Inc. where he began his career in Medicinal Chemistry. John holds a Ph.D. in organic chemistry from the Massachusetts Institute of Technology.

Tony Sarraino, Executive Director, Global Commercial Development for Anti-Infectives, Pfizer

Areas to be covered: Marketing, Sales, Commercial Development

Tony Sarraino is Executive Director, Global Commercial Development for Anti-Infectives at Pfizer responsible for both management of the Global Asset Teams for marketed brands as well as the new product development portfolio. He has more than 25 years of industry experience in Sales, Marketing and Business Development in a variety of therapeutic areas including antibacterials, antivirals, transplant and metabolic diseases. Tony brings a unique perspective to product development with his experience in successfully launching/marketing products in Canada, US and Globally to provide insights on drivers to success in building successful brands. He obtained his B. Commerce (Honors) in Finance from the University of Manitoba and a license from the Canadian Securities Institute.

Thomas Vihtelic, D.V.M., Ph.D., Director Experimental Therapeutics, MPI Research

Areas to be covered: Preclinical Development – Efficacy Models

John serves as head of the Pharmaceuticals Research department at Sirtris where he is accountable for Thomas S. Vihtelic, D.V.M., Ph.D., joined MPI Research in April 2008 as a Study Director in Experimental Therapeutics. He received his degree in veterinary medicine from Michigan State University and doctorate in molecular genetics from the University of Notre Dame. His doctoral research focused on characterization of Drosophila retinal degeneration genes and was followed by postdoctoral work at the University of Chicago (Department of Ophthalmology and Visual Sciences) and the Massachusetts Eye and Ear Infirmary (Howe Laboratory of Retina Molecular Genetics) using mouse retinal degeneration mutants and transgenic lines. Prior to joining MPI Research, Dr. Vihtelic was Research Associate Professor of Biology at the University of Notre Dame where he utilized molecular genetic strategies in the zebra fish model to study ocular lens and retinal development. During this time, he also developed a model of light-induced photoreceptor degeneration to study adult stem cell roles in the regenerating retina. Dr. Vihtelic currently serves as Director of the Experimental Therapeutics group at MPI Research.

Greg Wiederrecht, Ph.D., Vice President and Head of External Affairs (ESA), Merck Research Laboratories, Division of Merck & Co., Inc.

Areas to be covered: Licensing

Dr. Greg Wiederrecht is the Vice President and Head of External Scientific Affairs (ESA) in the Merck Research Laboratories division of Merck & Co., Inc. where he has been employed for the past 21 years. ESA is responsible for the scientific assessment of all licensing, partnering, and acquisition opportunities for Merck. Dr. Wiederrecht's responsibilities include the management of a group of 80 scientists and administrators, distributed worldwide and divided by various therapeutic and platform areas, who identify and assess opportunities outside of Merck's walls. Dr. Wiederrecht holds a B.S. degree from the University of California, Irvine and a PhD in biochemistry from M.I.T. Before joining Merck in 1989, he was a Helen Hay Whitney Post-Doctoral Fellow and an American Cancer Society Senior Post-Doctoral Fellow at Caltech. Dr. Wiederrecht has published 48 peer reviewed manuscripts and book chapters and has been an invited speaker at more than 50 conferences.

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MassBio, a not-for-profit organization that represents and provides services and support for the Massachusetts biotechnology industry, is committed to advancing the development of critical new science, technology and medicines for patients worldwide.



BIOCOM is the largest regional life science association in the world, representing more than 550 member companies in Southern California. We focus on initiatives that positively influence the development and delivery of innovative products that improve health and quality of life.



Delaware BioScience Association is a unified voice for Delaware's thriving bio community, dedicated to facilitating growth of the life science industry, advancements in research as well as supporting education initiatives in Delaware and the surrounding region.



BayBio is Northern California's life science association. We support the regional bioscience community through advocacy, enterprise support, and enhancement of research collaboration. We support entrepreneurship, science education and life science career development.

Biotechnology

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The Biotechnology Association of Alabama exists to promote biotechnology innovation by creating a favorable scientific, business and legislative environment that will facilitate the growth of emerging and existing companies while attracting new biotechnology opportunities to Alabama.



KansasBio - A unified voice for the Kansas bioscience community.

medicon valley alliance

Creating Opportunities

Medicon Valley Alliance - Cluster organisation for the Danish-Swedish life science cluster Medicon Valley. As non-profit organisation, Medicon Valley Alliance carries out initiatives to further develop the region on behalf of the life science community.



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Speid & Associates, Inc.

www.drugstomarket.com

Speid & Associates is a regulatory affairs and drug development consultancy. The company has expertise in global, international and US regulatory affairs and drug development. Dr. Speid is the principal consultant. The company works with expert associates in the US and abroad. Speid & Associates provides services to companies at all stages of the drug development pathway, on all indications, and types of therapeutics. The company is based out of San Diego, California.

Co-Chairs

Michal Preminger, Ph.D., MBA

Executive Director, Harvard University Office of Technology Development (OTD)

Michal Preminger, PhD, MBA is currently the Executive Director of the Harvard Office of Technology Development (OTD) at Harvard Medical School. Michal Preminger joined OTD in 2005. Prior to joining Harvard, she held a number of business development and technology development positions at Compugen, most recently as Vice President of Protein Therapeutics, responsible for the business management of the company's emerging drug discovery pipeline. Previously, Michal held several marketing and business development in the hi-tech industry, among others for Lucent Technologies. Michal also co-founded Anima Cell Metrology, a biotechnology startup focused on the real-time identification of proteins as they are synthesized in living cells. Michal holds an undergraduate degree in Medicine from the Hebrew University School of Medicine, a PhD from the Weizmann Institute of Science, and an MBA from INSEAD in Fontainebleau, France.

Lorna Speid, B.Pharm.(Hons.), M.R.Pharm.S., Ph.D., RAC

President, Speid & Associates, Inc.

Lorna Speid, B.Pharm.(Hons). M.R.Pharm.S., Ph.D., RAC is President of Speid & Associates, Inc. a regulatory and drug development consultancy based in San Diego, California. She works with small and large pharmaceutical companies, assisting them at the various stages of the drug development process, including US, European, international and global strategic regulatory affairs. Dr. Speid has an excellent track record of success in regulatory affairs, and is considered an expert in her field. She has registered therapeutics internationally, and has experience with all the major regulatory authorities. She has experience with many therapeutic areas including oncology, diabetes and pulmonary.

Dr. Speid began her career as a pharmacist in the UK, after which she completed a Ph.D. at the Centre for Medicines Research International, into the Safety Assessment of Medicines, Pre and Post Marketing. She has worked for large as well as small pharma companies, including Sanofi-Winthrop in the UK (now Sanofi-Aventis), Ciba Geigy and Novartis in Switzerland (at Headquarters). Small companies that she has worked for include Valentis, Inc. (Director of Regulatory Affairs), NewBiotics (Vice President Regulatory Affairs and Project Management), and Avera, Inc. (Vice President of Regulatory Affairs). Dr. Speid was an officer at the last two companies. She has a Bachelor of Pharmacy degree from the University of London, UK (Kings College), and a Ph.D. from the University of Wales, College Cardiff, UK.

Dr. Speid is the author of *Clinical Trials: What Patients and Healthy Volunteers Need to Know* which is published by Oxford University Press. The book is written for patients and healthy volunteers, and explains the process of clinical trials, equipping them to participate in clinical trials more effectively. The book is being marketed globally.