

## 2<sup>ND</sup> AAPS/DDDI REGIONAL MEETING

# Evolving Strategies for Drug Candidates Optimization in a Changing Pharmaceutical Landscape

August 4, 2017 (8 a.m. – 5 p.m.)

Pharmacy Hall, Room N103/111

University of Maryland School of Pharmacy, Baltimore, MD

**8:00 – 8:45 a.m.** Registration

**8:45 – 9:00 a.m.** Welcome and Opening Remarks

**Hazem Hassan, PhD**

Assistant Professor, Department of Pharmaceutical Sciences  
University of Maryland School of Pharmacy

**Steven Fletcher, PhD**

Associate Professor, Department of Pharmaceutical Sciences  
University of Maryland School of Pharmacy

**Sunny Bhardwaj, PhD**

Chair, DDDI Regional Meeting/ Senior Scientist, Merck & Co., Inc.

**Moderator:** **Steven Fletcher, PhD**

**9:00 – 9:50 a.m.** Keynote Speaker 1

*“Enabling Rapid Progression of New Molecular Entities from Discovery to Development”*

**Mike Hageman, PhD**

Former Exec. Director  
Discovery Pharmaceuticals Bristol-Myers Squibb

**9:50 – 10:40 a.m.** Keynote Speaker 2

*“Early Phase Development and Population PK and its Value”*

**Capt. Edward D. Bashaw, PharmD**

Director, Division of Clinical Pharmacology-3  
U.S. Food and Drug Administration

**10:40 – 11:10 a.m.** Beverage Break/Networking Session

**11:10 – 12:00 p.m.** Keynote Speaker 3

*“Enabling the Pipeline through Advanced Predictive Analysis Tools to Build Fundamental Understanding in Early Small Molecule and Peptide Development”*

**Justin Pennington, PhD**

Director, Pharmaceutical Sciences and Clinical Supply  
Merck Research Laboratories

**12:00 - 1:15 p.m.** Lunch and Networking

1:15 – 2:45 p.m. HOT TOPIC SESSION 1

*Transforming skillsets in early development to meet the changing NCE/NBE landscape in discovery space*

**Moderator:**

**Chitra Telang, PhD**

Senior Principal Scientist, Preformulation and Physical  
Pharmaceutics - Material and Analytical Sciences Department  
Boehringer Ingelheim Pharmaceuticals

**Speakers/Panelists:**

*“Analytics of Biomolecules: Some Considerations when  
Transitioning from Analysis of Small (NCE) Molecules”*

**Vladimir Papov, PhD**

Boehringer Ingelheim Pharmaceuticals

*“Mechanistic Computational Models to Evaluate the  
Druggability and Safety of the Wnt Pathway Using an  
NBE Approach”*

**Jonathan Phillips, PhD**

Toxicology Fellow, Discovery & Investigative Toxicology Section  
Vertex Pharmaceuticals

*“A Multi-Faceted Approach towards the Discovery of New  
Small-Molecule Antineoplastics”*

**Steven Fletcher, PhD**

Associate Professor, Department of Pharmaceutical Sciences  
University of Maryland School of Pharmacy

2:45 – 3:15 p.m. Beverage Break

**SPEED NETWORKING**

*A fun, fast event that provides the perfect opportunity for:*

- *Meeting attendees to expand their professional contacts through brief, structured 1-on-1 exchanges*
- *Students to practice their “elevator pitches” to potential future employers*
- *Academics to share their latest research innovations with industry partners*
- *Biopharmaceutical professionals to brainstorm with colleagues across the industry and the discovery/development spectrum*
- *All participants to learn and engage with one another in a relaxed, friendly environment*

3:15 – 4:45 p.m. HOT TOPIC SESSION 2

*Academic collaboration and preparing for the discovery support role in industry*

**Moderator:**

**Patrice Jackson-Ayotunde, PhD**

Associate Professor, School of Pharmacy and Health Professions  
University of Maryland Eastern Shore

**Speakers/Panelists:**

*"Pharma-Academia Interfacing: A Report from the Front Line"*

**David Rodrigues, PhD**

Research Fellow, Pharmacokinetics, Dynamics & Metabolism  
Department  
Pfizer Inc.

*"Improving Priority Drugs by Reduced Dose and Toxicities: Industry-Academic Collaborations for Increased Access to Medicines"*

**Joseph M.D. Fortunak, PhD**

Associate Professor, Department of Chemistry  
Howard University

**4:45 – 5:00 p.m.**

Closing Remarks

**Sunny Bhardwaj, PhD**

Senior Scientist, Discovery Pharmaceutical Sciences Group  
Merck & Co

## SPEAKERS' BIOGRAPHIES



**Mike Hageman, PhD**  
Former Exec. Director  
Discovery Pharmaceuticals Bristol-Myers Squibb

Dr. Hageman has over 30 years of experience within the pharmaceutical industry, including Upjohn, Pharmacia, Pfizer, and for the last 11 years, Bristol-Myers Squibb. He has worked within Discovery organizations for the design and selection of developable molecules, both small drug-like molecules and larger protein biologics. Physicochemical property prediction and characterization, including preformulation and design of enabled formulations for enhanced bioavailability, were critical for successful progression of the drug candidates. He obtained his BS in pharmacy and PhD in pharmaceutical chemistry from the University of Kansas. He has been an adjunct professor at Purdue University, University of Kansas, and University of Utah, serving on six different thesis committees. Dr. Hageman is an editor for the *Journal of Pharmaceutical Sciences* and chairs the Pharmaceuticals Advisory Committee for the PhRMA Foundation. He has also served as chair of the Physical Pharmacy and Biopharmaceutics Section for AAPS and been involved in the organization of over 10 symposia at AAPS sponsored meetings.



**Capt. Edward D. Bashaw, PharmD**  
Director  
Division of Clinical Pharmacology-3  
U.S. Food and Drug Administration

Dr. Bashaw received his BS in pharmacy and Doctor of Pharmacy from the University of Kentucky in 1986. Upon completion of a residency at the National Institutes of Health-Clinical Center, Dr. Bashaw accepted a commission in the United States Public Health Service as a reviewer in the then Division of Biopharmaceutics. In his 28 years at the FDA, he has been a primary reviewer, team leader, and a deputy division director across a number of therapeutic areas including, but not limited to neuropharmacology, surgical drugs, anti-inflammatory, over-the-counter, and pulmonary drugs, in addition to his current responsibilities. Currently, in addition to his primary role as a division director overseeing 27 PharmD and PhD reviewers, he serves as a subject matter expert for clinical pharmacology in the development of FDA policies related to the development of dermatology and orphan drug products.



**Justin Pennington, PhD**  
Director  
Pharmaceutical Sciences and Clinical Supply  
Merck Research Laboratories

Dr. Pennington is a director at Merck Research Laboratories within the Pharmaceutical Sciences and Clinical Supply Division with the responsibility of overseeing small molecule and peptide analytical groups in Rahway, N.J. and West Point, Pa. He obtained his PhD in pharmaceutical chemistry from the University of Kansas, Lawrence, where he developed chromatographic expertise, including high-pressure column packing and fabrication of capillary based monolithic silica columns. His dissertation research focused on the development of fluorescent stable isotope tagging strategies for proteins containing DOPA. Prior to his PhD, he completed his bachelor's degree in chemistry and math at Briar Cliff University in Sioux City, Iowa. After graduation from Kansas, he joined Merck (Schering-Plough) in the Respiratory Product Development group, where held roles of increasing responsibility prior to his current role. His research interests include the study of in-vitro predictive technologies and the use of mathematical modeling and quantitative mass spectrometry for uniformity analysis and trace level analysis. In addition to actively publishing manuscripts and conference presentations, Dr. Pennington is active in the external scientific community as a USP expert committee member, and is a member of the executive committee and current president of Eastern Analytical Symposium.



**Vladimir Papov, PhD**  
Boehringer Ingelheim Pharmaceuticals

Dr. Papov received his PhD in biological chemistry in 1996 from MIT in Cambridge, Mass. where he studied the structure and function of proteins via mass spectrometry under Prof. Klaus Biemann. Following his PhD, he did a post-doc with Prof. William Konigsberg in the Molecular Biophysics and Biochemistry Department at the Yale Medical School, where he worked to better understand the function of hnRNP proteins. He was initially hired by the DMPK department at Boehringer Ingelheim in 1997, where he worked mainly with small molecule candidate drugs (NCEs), but soon after moved to Research in order to start up a new proteomics laboratory to take advantage of the explosion in DNA sequence knowledge at that time. His work in Research revolved around novel drug target identification and validation using a combination of molecular biology, mass spectrometry and bioinformatics techniques. In 2006, he returned to Development and joined Analytical Sciences as a department expert on biologics. With his return to Development, he first provided expertise on mass spectrometry based structural elucidation of small molecule NCEs and related impurities and degradants and also established the capability for quantifying genotoxic impurities at sub-ppm levels by mass spectrometry. Since the formation of the NBE Development Skill Center at BI Ridgefield in 2010, he has been the Development project representative for all internal NBE Development projects and responsible for all local analytics required to support early GLP nonclinical safety studies. Before he rejoined Development in 2006, he had already established a collaboration with the Mechanistic Toxicology group in the Nonclinical Safety Department to identify and validate novel safety and mechanistic biomarkers using mainly mass spectrometric approaches and this collaboration continues today using the latest tools such as immunoenrichment prior to mass spectrometry analysis (aka "immuno-MRM").



**Jonathan Philips, PhD**  
Toxicology Fellow  
Discovery & Investigative Toxicology Section  
Vertex Pharmaceuticals

Dr. Phillips has spent the past 10 years enabling safe clinical development of large and small molecule drugs. At Vertex, he is responsible for preclinical safety for the early discovery pipeline in Boston, including joint development of gene editing approaches for various indications with CRISPR Therapeutics. Prior to Vertex, Dr. Phillips was a sr. principal scientist in Nonclinical Drug Safety at Boehringer Ingelheim Pharmaceuticals, where he led the Biophysics, Modeling & Simulation group. Dr. Phillips holds a PhD in cell biology from the University of Massachusetts Graduate School of Biomedical Sciences. He performed his graduate work with the NASA Graduate Student Research Program, studying cellular mechanotransduction and was awarded a Bioastronautics and Fundamental Space Biology postdoctoral fellowship by the Universities Space Research Association. He completed postgraduate research at NASA Ames Research Center, where he was appointed as a fellow of the NASA Postdoctoral Program.



**Steven Fletcher, PhD**  
Associate Professor  
Department of Pharmaceutical Sciences  
University of Maryland School of Pharmacy

Dr. Fletcher is a tenured Associate Professor of Medicinal Chemistry at the University of Maryland School of Pharmacy. His research program focuses on the disruption of aberrant protein-protein interactions with small-molecules, with a particular emphasis on the discovery of new treatments for cancer. He has published 79 papers in high impact, peer-reviewed journals in the fields of medicinal chemistry and synthetic organic chemistry, and is the inventor or co-inventor on 4 patents. He was named the University of Maryland AACP Teacher of the Year in 2014. Dr. Fletcher was educated at the University of Cambridge, UK, where he graduated in 2000 with a Master of Natural Sciences degree in chemistry. In 2004, he received his PhD under the direction of Professor Andrew D. Miller at Imperial College London, UK, on the development of novel liposomal systems for gene therapy. He then moved to Yale University, CT, where he worked with Professor Andrew D. Hamilton on the discovery of novel farnesyltransferase inhibitors as potential new anti-cancer agents and anti-malarials. In 2007, he continued his post-doctoral studies at the University of Toronto with Professor Patrick T. Gunning on the disruption of aberrant Stat3 signaling with small-molecules. Steven moved to the University of Maryland in late 2009 as an Assistant Professor, and was recently promoted with tenure. He has been an active member of the Drug Discovery and Development Interface (DDDI) section of the American Association of Pharmaceutical Scientists (AAPS) and is currently the Chair Elect of the Content Advisory Committee for the AAPS Newsmagazine.



**David Rodrigues, PhD**  
 Research Fellow  
 Pharmacokinetics, Dynamics & Metabolism Department  
 Pfizer Inc.

Dr. Rodrigues has been in the pharmaceutical industry for 27 years and now serves as research fellow at Pfizer (Pharmacokinetics, Dynamics & Metabolism Department; Groton, Conn.). He is head of the Transporter Sciences Group. Before joining Pfizer, he worked at BMS, Merck, Abbott, and Searle; serving on managerial (director, senior director, and executive director) and research (fellow) ladders. Prior to joining the pharmaceutical industry, Dr. Rodrigues studied in England and graduated with a BS degree (Kingston-Upon-Thames Polytechnic, Kingston, Surrey) and a PhD (Surrey University, Guildford, Surrey). He has (co-)authored nearly 20 book chapters, over 120 peer-reviewed manuscripts, and has presented at over 60 symposia/meetings. In 2009, he was inducted as an AAPS Fellow (American Association of Pharmaceutical Scientists). He has served on the editorial board of numerous drug metabolism journals, is currently associate editor of *Xenobiotica*, sits on the editorial board of *Current Drug Metabolism*, and has edited/co-edited four books (three related to drug interactions and one on the topic of drug metabolism). Dr. Rodrigues also serves as adjunct professor at the University of Rhode Island, School of Pharmacy.



**Joseph M.D. Fortunak, PhD**  
 Associate Professor, Department of Chemistry  
 Howard University

Dr. Fortunak has over 20 years of experience in pharmaceutical industry, including launch of quite a number of New Chemical Entities at GSK (10 years), Dupont Pharma (eight years), and Abbott Labs (four years). His last position was the head of global chemical development at Abbott Labs. He is currently an associate professor of chemistry & pharmaceutical sciences at Howard University, Washington, DC. The priority of his research group is to increase global access to medicines. His group creates new, green chemistry for producing critical medicines that decreases cost and waste. This technology is transferred to generic companies in low- and middle-income countries to bring down the cost and increase availability of critical medicines. In Africa, his group teaches drug companies, national drug regulators, and university faculty about current good manufacturing practice (cGMP), drug development, writing and reviewing regulatory submissions, and developing robust, reliable generic formulations. Additionally, Dr. Fortunak teaches at the St. Luke Foundation / Kilimanjaro School of Pharmacy, which is a United Nations ANDI Center of Excellence in drug manufacturing and training. Dr. Fortunak received his PhD in organic chemistry from the University of Wisconsin-Madison and his postdoctoral training from Cambridge University.

## Regional Planning Committee



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 Eastern Shore  
 School of Pharmacy



Annette Bak, PhD  
 AstraZeneca



Sunny Bhardwaj, PhD  
 Merck & Co., Inc.  
 (Chair)



Steven Fletcher, PhD  
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