Session I: Evaluation of FY 18 Generic Drug Research Priorities

“Challenges in BCS-based biowaivers”

James Polli, Ph.D.  
Professor and Ralph F. Shangraw/Noxell Endowed Professor in Industrial Pharmacy and Pharmaceutics  
NIPTF and University of Maryland School of Pharmacy

“Bioassays for Establishing Equivalence; Linking API and Formulation to their Biological Effect.”

Sid Bhoopathy, Ph.D.  
Chief Operating Officer  
Absorption Systems

“Non-Clinical Tools For In Vitro-In Vivo Correlation (IVIVC) and Bioequivalence Assessment of Ophthalmic Products”

Vatsala Naageswaran, M.S.  
Vice President Corporate Development  
Absorption Systems

“Critical issues in the use and evaluation of excipients in dosage forms such as pediatric, geriatric and abuse deterrent dosage forms”

Stephen W. Hoag, Ph.D.  
Professor of Pharmaceutical Sciences  
NIPTF and University of Maryland

“Advances in BA/BE and Dissolution Methodology”

Gordon Amidon, Ph.D.  
William I. Higuchi Distinguished University Professor of Pharmaceutical Sciences  
Charles R. Walgreen Jr. Professor of Pharmacy and Professor of Pharmaceutical Sciences  
University of Michigan, College of Pharmacy

Session II: Considerations for FY 19 Generic Drug Research Priorities

“Off-Label Use of Generic Drugs in Pediatric Populations”

Ilene Harris, Ph.D.  
Vice President and Chief Research Officer  
IMPAQ International, LLC
“Enhancing Comprehension of Generic Drug Information among Patients and Caregivers with Low Health Literacy”

**Jingjing Qian, Ph.D.**
Assistant Professor
Auburn University Harrison School of Pharmacy

“A Model- and Systems-Based Approach to Efficacy and Safety Questions Related to Generic Substitution”

**Stephan Schmidt, B.Pharm, Ph.D., F.C.P.**
Certara Professor
Associate Professor & Associate Director
Associate Chair
Center for Pharmacometrics & Systems Pharmacology
Department of Pharmaceutics Lake Nona (Orlando)
University of Florida

“A Rigorous Certificate Program on Quality by Design and Quality Culture”

**Stephen R. Byrn, Ph.D.**
Charles B. Jordan Professor of Medicinal Chemistry
NIPTE and Purdue University

“Anticipated Regulatory Science Challenges in Democratizing Generic Drugs for Global Health”

**Eugene Choi, Ph.D.**
Executive Director
Virginia Commonwealth University