

Center for Drug Evaluation and Research (CDER)
Food and Drug Administration
Department of Health and Human Services

**Generic Drug User Fee Amendments of 2017 Regulatory Science Initiatives:
Request for Public Input for FY 2019 Generic Drug Research
Public Workshop**

Public Comment Period - Presenters

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

NIPTE 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 Naageshwaran, 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

NIPTE 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

IMPACT 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