2017 AAM CMC Workshop

Chemistry, Manufacturing and Controls

Tuesday, May 23, 2017 - WORKSHOP DAY 1

7:00 a.m. – 8:15 a.m.	***2017 AAM CMC Workshop Registration*** – Grand Ballroom Foyer D-H ***Networking Breakfast*** – Salon D
8:15 a.m. – 8:45 a.m.	**Opening Remarks – AAM** ***David Gaugh, R.Ph.*** Senior Vice President, Sciences & Regulatory Affairs, AAM
8:45 a.m. – 9:15 a.m.	**Office of Pharmaceutical Quality Keynote Address** ***Michael Kopcha, Ph.D., R.Ph.*** Director, Office of Pharmaceutical Quality (OPQ), FDA
9:15 a.m. – 10:15 a.m.	**OPQ's Lifecycle Approaches – Knowledge Transfer NDA's to ANDA's** ***Susan Rosencrance, Ph.D.*** Director, Office of Lifecycle Drug Products (OLDP), OPQ, FDA ***Robert Iser, M.S.*** Director, Office of Process and Facilities (OPF), OPQ, FDA
10:15 a.m. – 10:45 a.m.	***Networking Refreshment Break*** – Grand Ballroom Foyer D-H

Complex Products 10:45 a.m. - 12:15 p.m. Salon E-H	**Comparability Protocol and Post Approval Changes – Decreasing Regulatory Burden and How Industry Can Engage in Rich Dialogue with FDA** 10:45 a.m. - 12:15 p.m. White Flint Amphitheater (lower level)
Moderator: ***Molly Rapp*** Vice President, Regulatory Affairs, US Innovation and Development, Generics and Standard Solutions, Fresenius Kabi USA LLC ***Andre Raw, Ph.D.*** Senior Scientific and Policy Advisor, OLDP, OPQ, FDA ***Joseph Glajch, Ph.D.*** Director, Analytical Development, Momenta Pharmaceuticals ***Jeff Jiang, Ph.D. (Panelist)*** Deputy Director, Division of Therapeutic Performance, Office of Research and Standards, Office of Generic Drugs (OGD), FDA	Moderator: ***Dominique Kendrick, R.Ph., MBA, R.A.C.*** President, EverestGreen Partners, Inc. ***Andrew Langowski*** Branch Chief (Acting), Division of Post Marketing Activities II, OLDP, OPQ, FDA ***Kiran Krishnan, Ph.D.*** Senior Vice President, Global Regulatory Affairs, Apotex Inc.

12:15 p.m. – 1:30 p.m. ***Luncheon*** – White Oak (lower level)

Regulatory Expectations for Drug-Device Combination Products *1:30 p.m. - 2:30 p.m.* *Salon E-H*	**Excipients: Impact on Overall Product Quality** *1:30 p.m. - 2:30 p.m.* *White Flint Amphitheater (lower level)*
Moderator: ***Scott Tomsky, M.S.*** Vice President, Regulatory Affairs, Generics North America, Teva Pharmaceuticals ***Ashley Boam, MSBE, BSE*** Director, Office of Policy for Pharmaceutical Quality (OPPQ), OPQ, FDA ***Andrew LeBoeuf, M.S., J.D.*** Regulatory Counsel, Division of Policy Development, Office of Generic Drug Policy, OGD, FDA ***Kimberly Witzmann, M.D. (Panelist)*** Team Lead, Respiratory and Drug-Device Combination Products, Office of Research and Standards, Division of Therapeutic Performance, OGD, FDA	Moderator: ***Marcy MacDonald, R.A.C.*** Vice President, Regulatory Affairs Impax Laboratories ***Sruthi King, Ph.D.*** Pharmacology Toxicology Team Lead, Division of Clinical Review, Office of Bioequivalence, OGD, FDA ***Priscilla Zawislak*** Global Regulatory Affairs Advocacy Manager, The Dow Chemical Company

2:30 p.m. – 3:00 p.m. ***Networking Refreshment Break*** – Grand Ballroom Foyer D-H

3:00 p.m. – 5:00 p.m.

Industry's Corner: Case Studies

Moderator: ***Siva Vaithiyalingam, Ph.D.***
Vice President, Regulatory Affairs, North America, Cipla LTD

Devices for Drug-Device Combo Products – How Similar is Similar
Cory Wohlbach
Senior Director, US Gx Regulatory Affairs, Teva Pharmaceuticals

API Starting Material – Impact on 1st Cycle Approvals
Aloka Srinivasan, Ph.D.
Vice President, Regulatory Affairs, Lupin Pharmaceuticals, Inc.

In-Use Stability Requirements
Andrea Redd, B.S.
Director, Regulatory Affairs Combination Products, Fresenius Kabi USA LLC

Stratified Sampling versus Blend Uniformity Testing
Ravi Harapanhalli, Ph.D.
Senior Vice President, Global Regulatory Affairs, Amneal Pharmaceuticals

5:00 p.m. – 7:00 p.m.

Networking Reception – Grand Ballroom Foyer D-H & Terrace

Wednesday, May 24, 2017 - WORKSHOP DAY 2

7:00 a.m. – 8:00 a.m.

2017 AAM CMC Workshop Breakfast – Salon D

8:00 a.m. – 9:30 a.m.

How to Facilitate First Cycle Approvals – Recommendations and Expectations

Moderator: ***Scott Tomsky, M.S.***
Vice President, Regulatory Affairs, Generics North America, Teva Pharmaceuticals

Yaodong (Tony) Huang, Ph.D.
Reviewer and Quality Assessment Lead, Division of Process Assessment, OPF, OPQ, FDA

Mayra Pineiro-Sanchez, Ph.D.
Quality Assessment Lead, Division of Immediate Release Products, OLDP, OPQ, FDA

Kimberly Raines, Ph.D.
Branch Chief (Acting), Division of Biopharmaceutics Branch III, Office of New Drug Products (ONDP), OPQ, FDA

Giuseppe Randazzo, M.S.
Director, Office of Program and Regulatory Operations (OPRO), OPQ, FDA

Marla Stevens-Riley, Ph.D.
Master Microbiology Reviewer, Division of Microbiology Assessment, OPF, OPQ, FDA

9:30 a.m. – 10:00 a.m.

Networking Refreshment Break – Grand Ballroom Foyer D-H

10:00 a.m. – 11:00 a.m. **Quality Metrics – Where is Industry Going?**

Moderator: ***Scott Lassman***
Partner, Goodwin Procter LLP

Deborah Autor
Head of Strategic Global Quality & Regulatory Policy, Mylan
AAM Representative

Brian Dillion
Vice President, Quality and Regulatory, Alcami Corporation
PBOA Representative

Máiréad Goetz
Head of Compliance, Novartis Pharmaceuticals Corporation
International Society for Pharmaceutical Engineering (ISPE) Representative

11:00 a.m. – 11:15 a.m. ***Networking Refreshment Break*** – Grand Ballroom Foyer D-H

DMF Related Impediments to First Cycle Approvals of ANDAs 11:15 a.m. - 12:15 p.m. Salon E-H	**Setting Proper Impurities Limits… Including Genotoxic Impurities** 11:15 a.m. - 12:15 p.m. White Flint Amphitheater (lower level)
Moderator: ***Kiran Krishnan, Ph.D.*** Senior Vice President, Global Regulatory Affairs Apotex Inc. ***Ramnarayan Randad, Ph.D.*** Chemist, Division of Lifecycle API, ONDP, OPQ, FDA ***Dan Snider Ph.D.*** Head of Research & Development-Morgantown Mylan Inc.	Moderator: ***Molly Rapp*** Vice President, Regulatory Affairs, US Innovation and Development, Generics and Standard Solutions, Fresenius Kabi USA LLC ***Elisabeth Kovacs*** Chief Scientific Officer, Chemistry and Analytical Sciences, Apotex Inc. ***Janet Vaughn*** Senior Director, Regulatory Affairs, Teva Pharmaceuticals

12:15 p.m. – 1:30 p.m. ***Luncheon*** – White Oak (lower level)

Process Validation: Lifecycle Approach *1:30 p.m. - 2:30 p.m.* Salon E-H	**Quality Aspects Related to Ophthalmic Products – Case Study** *1:30 p.m. - 2:30 p.m.* White Flint Amphitheater (lower level)
Moderator: ***Dominique Kendrick, R.Ph., MBA, R.A.C.*** President, EverestGreen Partners, Inc. ***Vidya Pai, Ph.D., M.S.*** Facility Reviewer and Acting Quality Assessment Lead, Division of Inspectional Assessment, OPF, OPQ, FDA ***Yubing Tang, Ph.D.*** Branch Chief (Acting), Process Assessment Branch V, Division of Process Assessment, OPF, OPQ, FDA	Moderator: ***Siva Vaithiyalingam, Ph.D.*** Vice President, Regulatory Affairs, North America, Cipla LTD ***Avin Lalmansingh, Ph.D.*** Quality Review Chemist, Division of Post Marketing Activities, OLDP, OPQ, FDA

2:30 p.m. – 3:00 p.m.	***Networking Refreshment Break*** – Grand Ballroom Foyer D-H
3:00 p.m. – 4:00 p.m.	**Trends: Data Integrity** Moderator***:*** ***Scott Tomsky, M.S.*** Vice President, Regulatory Affairs, Generics North America Teva Pharmaceuticals ***Tom Cosgrove, J.D.*** Director, Office of Manufacturing Quality, Office of Compliance (OC), FDA ***Robert Pollock, R.Ph., M.S.*** Senior Advisor, Outside Director to the Board Lachman Consultant Services, Inc.
4:00 p.m. – 4:15 p.m.	**Closing Remarks** ***David Gaugh, R.Ph.*** Senior Vice President, Sciences & Regulatory Affairs, AAM
4:15 p.m.	***Workshop Conclude***