Monday, November 6, 2017

USP Workshop *(separate registration)*

7:00 a.m. – 5:30 p.m.	***2017 Fall Technical Conference Registration*** - Grand Ballroom Foyer
8:30 a.m. – 8:45 a.m.	**Welcome and Introduction** – Salon A-C
8:45 a.m. – 9:30 a.m.	**Analytical Procedure Lifecycle and Statistics: Applied to Analytical Procedures/General Chapters**
9:30 a.m. – 10:15 a.m.	**Elemental Impurities**
10:15 a.m. – 10:30 a.m.	***Networking Refreshment Break*** - Grand Ballroom Foyer
10:30 a.m. – 11:15 a.m.	**USP Workshop Continues**
10:30 a.m. – 11:15 a.m.	**Closing Remarks**
11:30 a.m.	***Workshop Concludes***

Monday, November 6, 2017
2017 AAM Fall Technical Conference - Day 1

7:00 a.m. – 5:00 p.m.	***2017 Fall Technical Conference Registration*** - Grand Ballroom Foyer
11:30 a.m. – 1:00 p.m.	***Networking Welcome Lunch*** – White Oak
1:00 p.m. – 1:15 p.m.	**Welcome and Introductions** ***David Gaugh, RPh*** Senior Vice President, Sciences & Regulatory Affairs, AAM
1:15 p.m. – 1:45 p.m.	**State of AAM Address** ***Chester "Chip" Davis, Jr., JD*** President and CEO, AAM
1:45 p.m. – 2:30 p.m.	**State of OGD Address** ***Kathleen Uhl, PhD*** Director, Office of Generic Drugs (OGD), FDA
2:30 p.m. – 3:00 p.m.	***Networking Refreshment Break*** - Grand Ballroom Foyer
3:00 p.m. – 3:30 p.m.	**FDA Commissioner Keynote Address** ***Scott Gottlieb, MD*** Commissioner, FDA
3:30 p.m. – 4:00 p.m.	**State of OPQ Address** ***Giuseppe Randazzo, MS*** Director, Office of Program and Regulatory Operations (OPRO) Office of Pharmaceutical Quality (OPQ), FDA
4:00 p.m. – 4:30 p.m.	**State of ORA Address** ***Erika Anderson, JD, MPA*** Deputy Associate Commissioner for Regulatory Affairs (Acting), FDA
4:30 pm – 5:30 pm	**International Harmonization – IGBA Perspective** Moderator: ***David, Gaugh, RPh*** Senior Vice President, Sciences & Regulatory Affairs, AAM ***Nicholas Cappuccino, Jr., PhD*** Vice-President, Head of Quality and Scientific Affairs Dr. Reddy's Laboratories, Inc. Chair, Science Committee IGBA ***Sergio Napolitano, LLM*** Legal and External Relations Director Medicines for Europe
5:30 p.m. – 7:00 p.m.	***Networking Welcome Reception*** - Grand Ballroom Foyer

Tuesday, November 7, 2017

2017 AAM Fall Technical Conference - Day 2

7:00 a.m. – 8:00 a.m. ***Networking Breakfast*** – Salon A-C

8:00 a.m. – 9:00 a.m. **Rising Drug Prices: Opportunities for Generics**
Speaker(s) TBD

9:00 a.m. – 10:00 a.m. **GDUFA II Pre – ANDA Program**
Moderator: ***Kiran Krishnan, PhD***
Senior Vice President, US Regulatory Affairs, Apotex, Inc.
Robert Lionberger, PhD
Director, Office of Research Standards (ORS), OGD, FDA
Kris Andre, MS (panelist)
Senior Regulatory Project Manager, ORS, OGD, FDA

10:00 a.m. – 10:30 a.m. ***Networking Refreshment Break*** - Grand Ballroom Foyer

10:30 a.m. – 12:00 p.m. **Office of Generic Drugs GDUFA II Review Program Enhancements (Part I)**
Moderator: ***Scott Tomsky, MS, BS***
Vice President, Regulatory Affairs, Generics North America
Teva Pharmaceuticals
Kwadwo (Kojo) Awuah, PharmD
Team Leader, Division of Filing, Office of Regulatory Operations (ORO) OGD, FDA
Nicholas Daniel, PharmD
Regulatory Project Manager, DPM, ORO, OGD, FDA
Michael Folkendt, MS
Associate Director for Regulatory Affairs, OPRO, OPQ, FDA
Tiffany Houser, PharmD
Regulatory Project Manager, Division of Project Management (DPM), ORO, OGD, FDA
LCDR Andrew Kim, PharmD
Supervisory Project Manager, DPM, ORO, OGD, FDA
Heidi Lee, PharmD
Project Manager, Immediate Office (IO), ORO, OGD, FDA
CDR Vincent Sansone, PharmD, CPH
Deputy Director (Acting), ORO, OGD, FDA
Priya Shah, PharmD
Project Manager, IO, ORO, OGD, FDA
Edward Sherwood, BA
Director, ORO, OGD, FDA

12:00 p.m. – 1:30 p.m. ***Fall Technical Conference Luncheon*** - White Oak

1:30 p.m. – 3:30 p.m.

Office of Generic Drugs GDUFA II Review Program Enhancements (Part II)

Moderator: ***Scott Tomsky, MS, BS***
Vice President, Regulatory Affairs, Generics North America
Teva Pharmaceuticals
Kwadwo (Kojo) Awuah, PharmD
Team Leader, Division of Filing, Office of Regulatory Operations (ORO)
OGD, FDA
Nicholas Daniel, PharmD
Regulatory Project Manager, DPM, ORO, OGD, FDA
Michael Folkendt, MS
Associate Director for Regulatory Affairs, OPRO, OPQ, FDA
Tiffany Houser, PharmD
Regulatory Project Manager, Division of Project Management (DPM), ORO, OGD, FDA
LCDR Andrew Kim, PharmD
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Heidi Lee, PharmD
Project Manager, Immediate Office (IO), ORO, OGD, FDA
CDR Vincent Sansone, PharmD, CPH
Deputy Director (Acting), ORO, OGD, FDA
Priya Shah, PharmD
Project Manager, IO, ORO, OGD, FDA
Edward Sherwood, BA
Director, ORO, OGD, FDA

3:30 p.m. – 4:00 p.m.

Networking Refreshment Break - Grand Ballroom Foyer

4:00 p.m. – 6:00 p.m.

Expo Session

FDA Booths:

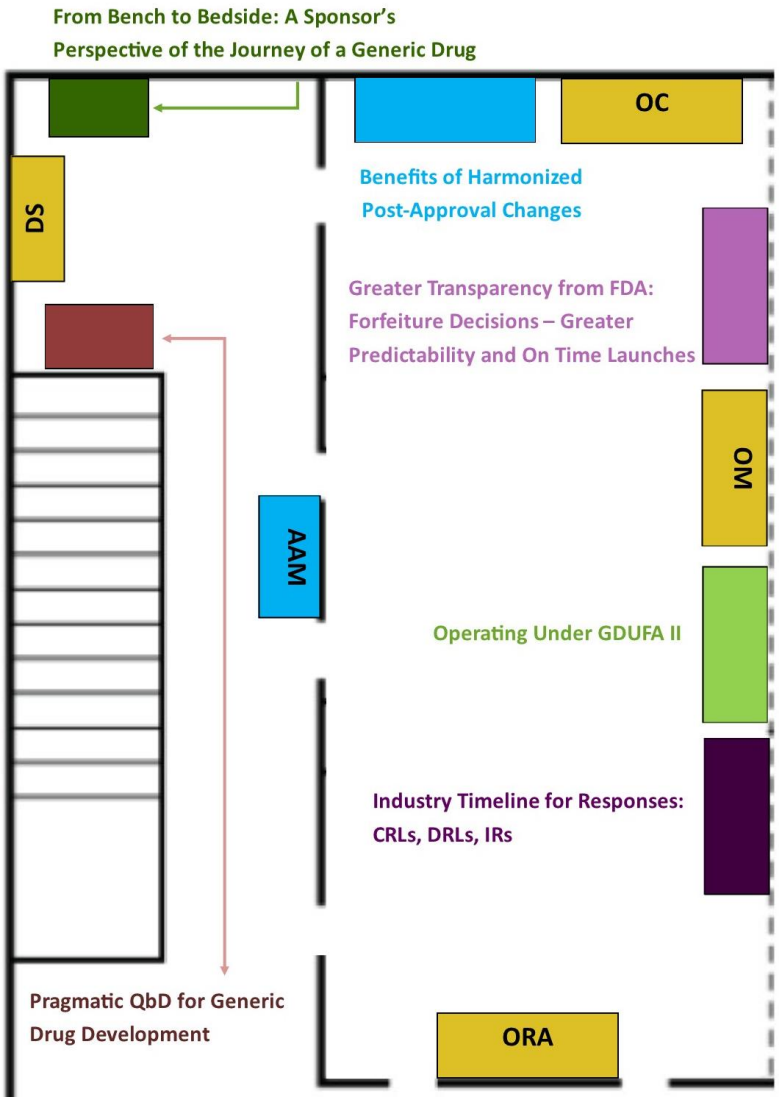
- Office of Management
- Drug Shortage Team
- Office of Compliance (invited)
- Office of Regulatory Affairs (invited)

Industry Booths:

- Association for Accessible Medicines
- Pragmatic QbD for Generic Drug Development
- Operating Under GDUFA II
- From Bench to Bedside: A Sponsor's Perspective of the Journey of a Generic Drug
- Benefits of Harmonized Post-Approval Changes
- Industry Timeline for Responses: CRLs, DRLs, IRs
- Greater Transparency from FDA: Forfeiture Decisions – Greater Predictability and On Time Launches

Expo Participants:

Germain Bryant, MA, Management Analyst, Facilities Team, Generics Branch, Division of User Fee Management & Budget Formulation, OM, FDA
CAPT Christine Bina, RPh, MPH, Team Leader, Drug Storage Staff, FDA
Amy Byrom, Associate Director, Regulatory Affairs Sandoz Inc.
Mitul Chatterjee, Assistant Vice President, CMC Regulatory Affairs, Amneal Pharmaceuticals
Sandra D'Agostino-Ferlisi, Associate Director Regulatory Affairs Intelligence and Training, Apotex Inc.
Pramod Dahibate, Vice President, Regulatory, Lupin Ltd.
Joyce Delgaudio, Executive Director, Regulatory Affairs Teva Pharmaceuticals
Candis Edwards, Senior Vice President, Clinical Regulatory Affairs, Amneal Pharmaceuticals
Cheryl Hawkins, Management Analyst, Division of User Fee Management & Budget Formulation, OM, FDA
Richard Holl, PhD, Director, Development Operations, Lupin Research Inc.
Evelyn Hong, PharmD, Program Manager, Division of User Fee Management and Budget Formulation, OM, FDA
Sudhir Kaushal, MPharm, Director, Regulatory Affairs, Lupin Pharmaceutical Inc.
John Kennedy, Manager, Regulatory Affairs, Sandoz Inc.
Maria Kim, DPT, Project Manager, Generics Branch, Division of User Fee Management & Budget Formulation, OM, FDA
Pavan Kumar, Director, CMC Regulatory Affairs, Amneal Pharmaceuticals
Michelle Lee-Bourner, Head Global Respiratory Regulatory, Regulatory Affairs, Mylan Inc.



Brian McCormick, General Counsel, Regulatory and Lifecycle, Teva Pharmaceuticals
Anna McDermott-Vitak, Senior Vice President, Corporate Development and Administration, AAM
Scott McGuinness, Regulatory Affairs Association III, Sandoz Inc.
Dattatraya (Datta) Nagargoje, General Manager, Regulatory Affairs, Mylan Inc.
Martina O'Sullivan, Head of Global Regulatory Affairs (Injectables), Mylan Inc.
Jill Pastore, Senior Director, Regulatory Affairs, Teva Pharmaceuticals
Alpesh Patel, Vice President, CMC Regulatory Affairs, Amneal Pharmaceuticals
Priyanka Pawar, Assistant Vice President, CMC Regulatory Affairs, Amneal Pharmaceuticals
Giseuda "Gisa" Perez, MBA, Generics Branch Chief, Division of User Fee Management and Budget Formulation, OM, FDA
Hanah Pham, PharmD, Facilities Team Lead, Generics Branch, Division of User Fee Management and Budget Formulation OM, FDA
Jyoti Sachdeva, PhD, Senior Director, Regulatory Affairs, Mylan Inc.
Greg Seitz, Director, Regulatory Affairs, Sandoz Inc.
Jewel Smith, Director, Operations, AAM
Olivia Souweine, Med, Management Analyst, Applications Team, Generics Branch, Division of User Fee Management and Budget Formulation, OM, FDA
Aloka Srinivasan, PhD, Vice President, Regulatory Affairs, Lupin Pharmaceutical Inc.
Santhanakrishnan Srinivasan, Senior Director, Project Management and Complex Product Development Amneal Pharmaceuticals
Adam Steinberg, PharmD, Regulatory Project Manager, US Regulatory Affairs, Apotex Inc.
Meghal Vakil, Regulatory Project Manager, Apotex Inc.
Janet Vaughn, Senior Director, Regulatory Affairs, Teva Pharmaceuticals
Katherine (Katie) Wilson, Director, Global Regulatory Affairs Policy, Mylan Inc.
CDR Leo Zadecky, RPh, Senior Program Officer, Drug Storage Staff, FDA

6:00 p.m. – 6:30 p.m. ***Networking Reception*** - Grand Ballroom Foyer

6:30 p.m. – 9:00 p.m. ***AAM Lip Sync Battle Dinner and Entertainment***

Wednesday, November 8, 2017
2017 AAM Fall Technical Conference - Day 3

7:30 a.m. – 8:30 a.m. ***Networking Breakfast*** – Salon A-C / White Oak

8:30 a.m. – 9:30 a.m. **Anatomy of an Expedited/Priority Review**
Moderator: ***Robert Pollock***
Senior Advisor, Outside Director to the Board
Lachman Consultants Services, Inc.
Kurt Karst, JD
Director, Hyman, Phelps & McNamara, P.C.
Scott Tomsky, MS, BS
Vice President, Regulatory Affairs, Generics North America
Teva Pharmaceuticals

9:30 a.m. – 11:00 a.m. **Data Integrity Issues in Today's Complex and Global Manufacturing Supply Chain**
Moderator: ***Derek Glover***
Head of Global Quality Systems and Compliance
Mylan Pharmaceuticals Inc.
Derek Smith, PhD
Branch Chief (Acting), Division of Inspectional Assessment
Office of Process and Facility (OPF), OPQ, FDA
Frances Zipp
President, Lachman Consultant Services, Inc.
LCDR Mahesh Ramanadham, PharmD, MBA, RPh (panelist)
Director (Acting), Division of Inspectional Assessment
OPF, OPQ FDA

11:00 a.m. – 11:30 a.m. ***Networking Refreshment Break*** - Grand Ballroom Foyer

11:30 a.m. – 12:00 p.m. **Update – Implementation of GDUFA II User Fees**
Moderator: ***Candis Edwards***
Senior Vice President, Regulatory Affairs, Amneal Pharmaceuticals
Donal Parks, MBA, MPM
Director, Division of User Fee Management and Budget Formulation,
Office of Management, FDA

12:00 p.m. – 1:30 p.m. ***Fall Technical Conference Luncheon*** - Salon A-B / White Oak

1:30 p.m. – 2:30 p.m. **Fall Technical Conference Breakout Sessions**

Excipients – Standards for Pharmaceutical Products Salon D-E	**The Path to Bioequivalence - Great Progress, Great Opportunities** Salon C	**Complexity of Retention Samples Selection in Non-Traditional Bioequivalence Studies** White Flint Amphitheater (lower-level)
Moderator: ***Ravi Harapanhalli, PhD*** Senior Vice President Global Regulatory Affairs Amneal Pharmaceuticals ***USP Speaker(s) TBD***	Moderator: ***Kiran Krishnan, PhD*** Senior Vice President US Regulatory Affairs, Apotex, Inc. ***Charles DiLiberti*** President Montclair Bioequivalence Services, LLC	Moderator: ***Siva Vaithiyalingam, PhD*** Vice President, Regulatory Affairs North America, Cipla LTD ***Nageshwar Thudi, PhD*** Director, Clinical Research and Development, Teva Pharm

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

3:00 p.m. – 4:00 p.m. **Fall Technical Conference Breakout Sessions**

Stability Guidance +3 Years: Where Are We Now? Salon D-E	**Drug Product Quality and the Impact of Extractables and Leachables** Salon C
Moderator: ***Molly Rapp*** Vice President, Regulatory Affairs US Innovation and Development, Generics and Standard Solutions, Fresenius Kabi USA LLC ***Marcy Macdonald, RAC*** Vice President, Regulatory Affairs Impax Laboratories	Moderator: ***Dominique Kendrick, RPh, MBA, RAC*** President, EverestGreen Partners, Inc. ***Diane Paskiet, MS*** Senior Director, Global Scientific Affairs West Pharmaceuticals ***Andrea Redd, BS*** Director, US Regulatory Affairs Fresenius Kabi USA, LLC

4:00 p.m. ***Conference Concludes***