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 F-H ***Robert Femia, PhD*** Senior Vice President, Science-Chemical Medicines, USP
8:45 a.m. – 9:30 a.m.	**Analytical Procedure Lifecycle and Statistics: Applied to Analytical Procedures/General Chapters** **Horacio Pappa, PhD, CQE** Director, Compendial Science-General Chapters, USP
9:30 a.m. – 10:15 a.m.	**Elemental Impurities** **Horacio Pappa, PhD, CQE** Director, Compendial Science-General Chapters, USP
10:15 a.m. – 10:30 a.m.	***Networking Refreshment Break*** – Grand Ballroom Foyer
10:30 a.m. – 11:15 a.m.	**Research and Innovation Activities** ***Mike Ambrose, PhD*** Director, Research & Innovation, USP
11:15 a.m. – 11:30 a.m.	**Closing Remarks** ***Nelufar Mohajeri, MA, MPhil*** Senior Director, Global Stakeholder Engagement, USP
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*** – Salon A-C
1:00 p.m. – 1:15 p.m.	**Welcome and Introductions** – Salon D-E ***David Gaugh,RPh*** Senior Vice President, Sciences & Regulatory Affairs, AAM
1:15 p.m. – 1:45 p.m.	**State of the Industry Address** ***Chester "Chip" Davis, Jr., JD*** President & CEO, AAM
1:45 p.m. – 2:30 p.m.	**State of OGD Address** ***Kathleen Uhl, MD*** 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** ***Ellen Morrison*** Assistant Commissioner, Medical Products and Tobacco Operations Office of Regulatory Affairs (ORA), 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

Moderator: ***Craig Burton***
Vice President, Policy, AAM
Alex Brill
CEO and Founder, Matrix Global Advisors, LLC
Allan Coukell
Senior Director, Health Programs, The Pew Charitable Trusts
Matthew Eyles
Senior Executive Vice President and Chief Operating Officer, AHIP

9:00 a.m. – 10:00 a.m.

GDUFA II Pre – ANDA Program

Moderator: ***Kiran Krishnan, PhD***
Senior Vice President, Global Regulatory Affairs, Apotex Corp.
Robert Lionberger, PhD
Director, Office of Research Standards (ORS), OGD, FDA
Kris Andre, MS (panelist)
Associate Director, Regulatory Affairs, ORS, OGD, FDA
Michele Crawley, MS, RAC (panelist)
Director, Regulatory Affairs, Cipla USA, Inc.

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
CDR Kwadwo (Kojo) Awuah, PharmD, RAC
Team Leader, Division of Filing Review
Office of Regulatory Operations (ORO), OGD, FDA
LT Nicholas Daniel, PharmD, BCPS
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

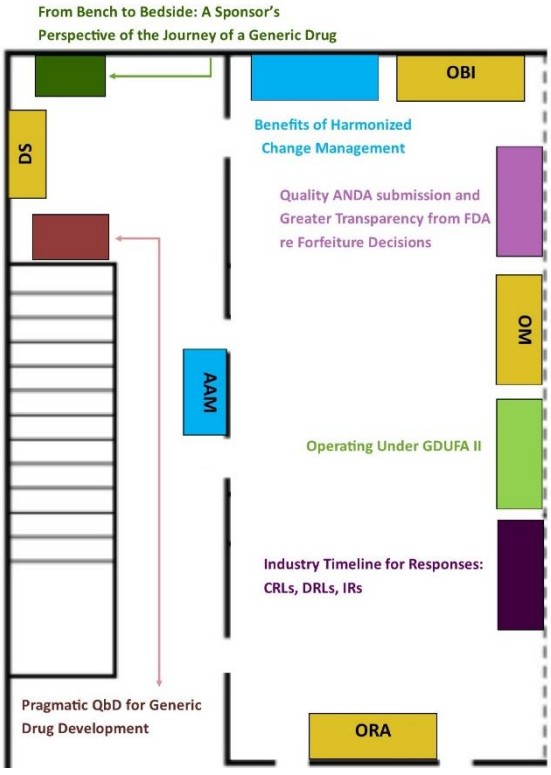
12:00 p.m. – 1:30 p.m. ***Fall Technical Conference Luncheon*** – Salon A-C/ White Oak

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
CDR Kwadwo (Kojo) Awuah, PharmD, RAC
Team Leader, Division of Filing Review
Office of Regulatory Operations (ORO), OGD, FDA
LT Nicholas Daniel, PharmD, BCPS
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

3:30 p.m. – 4:00 p.m. ***Networking Refreshment Break*** – Grand Ballroom Foyer

4:00 p.m. – 6:00 p.m. **Expo Session** – Salon A-C and Foyer C



FDA Booths:
- Office of Management
- Drug Shortage Team
- Office of Regulatory Affairs
- Office of Strategic Programs - Office of Business Informatics

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 Change Management
- Industry Timeline for Responses: CRLs, DRLs, IRs
- Quality ANDA Submission and Greater Transparency from FDA re Forfeiture Decisions

Expo Participants:

Erin Archer, JD, Senior Manager, State Government Affairs, AAM
Shawn Britton, Product Manager, Lupin Pharmaceuticals, Inc.
Kamilah Blackton, Writer-Editor, Office of Communications and Project Management, ORA, FDA
CAPT Tessa Brown, DHSc, MPH, RN, Deputy Director, Division of Data Management Services and Solutions (DDMSS), FDA
Germain Bryant, MA, Management Analyst, Facilities Team, Generics Branch, Division of User Fee Management and Budget Formulation, OM, FDA
Ethan Chen, PMP, MSE, MBA, Director (Acting), DDMSS, FDA
CAPT Christine Bina, RPh, MPH, Team Leader, Drug Storage Staff, FDA
Alonza Cruse, Director, Office of Pharmaceutical Quality Operations, ORA, FDA
Amy Byrom, Director, Regulatory Affairs, Fougera Pharmaceuticals Inc., a Sandoz Company
Sandra D'Agostino-Ferlisi, Associate Director Regulatory Affairs Intelligence and Training, Apotex Inc.
Joyce Delgaudio, Senior Director, Regulatory Affairs, Preapproval Generics, Teva Pharmaceuticals
Victoria Donnelly, Public Affairs Specialist, Office of Communications and Project Management, ORA, FDA
Madhuri Gupta, Manager, Global Regulatory Affairs, Apotex Inc.
Ravi Harapanhalli, PhD, Senior Vice President, Global Regulatory Affairs, Amneal Pharmaceuticals
Cheryl Hawkins, Management Analyst, Division of User Fee Management and Budget Formulation, OM, FDA
Richard Holl, PhD, Director, Development Operations, Lupin Research Inc.
LCDR 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 and Budget Formulation, OM, FDA
Anita Kumar, Director R&D, Amneal Pharmaceuticals
Pavan Kumar, PhD, Director, Regulatory Affairs, Amneal Pharmaceuticals
Gargi Lakhwani, MS, RAC Regulatory Affairs Associate, Amneal Pharmaceuticals
Michelle Lee-Bourner, Head Global Respiratory Regulatory, Regulatory Affairs, Mylan Inc.
Theresa Leh, Associate Director, Regulatory Affairs, Fougera Pharmaceuticals Inc., a Sandoz Company
Brian McCormick, General Counsel, Regulatory and Lifecycle, Teva Pharmaceuticals
Anna McDermott-Vitak, Senior Vice President, Corporate Development and Administration, AAM
Scott McGuinness, Bsc, MSc, QARA Regulatory Affairs Association III, Sandoz Inc.
Ann Marie Montemurro, Director, Division of Pharmaceutical Quality Programs, Office of Pharmaceutical Quality Operations, ORA, FDA
Dattatraya (Datta) Nagargoje, General Manager, Regulatory Affairs, Mylan Inc.
Milind Narvekar, MSc, PhD, Head, Regulatory Affairs, Apotex Research Pvt. Ltd
Martina O'Sullivan, Head of Global Regulatory Affairs (Injectables), Mylan Inc.
Jill Pastore, Senior Director, Regulatory Affairs, Teva Pharmaceuticals
Alpesh Patel, Vice President, Global Regulatory Affairs, Amneal Pharmaceuticals
Krushangi Patel, MS, Regulatory Affairs Specialist, Amneal Pharmaceuticals
Priyanka Pawar, PhD, Associate Vice President, Regulatory Affairs, Amneal Pharmaceuticals
Gisa Perez, MBA, Generics Branch Chief, Division of User Fee Management and Budget Formulation, OM, FDA
LCDR Hanah Pham, PharmD, Facilities Team Lead, Generics Branch, Division of User Fee Management and Budget Formulation, OM, FDA
Jonathan Resnick, Project Management Officer, DDMSS, FDA
Jyoti Sachdeva, PhD, Senior Director, Regulatory Affairs, Mylan Inc.
Jia Jian Shen, Project Management Officer, DDMSS, FDA
Jewel Smith, Director, Operations, AAM
Olivia Souweine, Med, Management Analyst, Applications Team, Generics Branch, Division of User Fee Management and Budget Formulation, OM, FDA
Adam Steinberg, PharmD, Project Manager, US Regulatory Affairs, Apotex Corp.
Kandasamy Subburaj, PhD, Director, Regulatory Affairs, Lupin Pharmaceuticals, Inc.
Meghal Vakil, Regulatory Project Manager, Apotex Corp.
Janet Vaughn, Senior Director, Regulatory Affairs, Teva Pharmaceuticals
Katherine (Katie) Wilson, Director, Global Regulatory Affairs Policy, Mylan Inc.
CDR Leo Zadecky, RPh, Senior Program Management 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*** – Salon D-E

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

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

8:30 a.m. – 9:30 a.m. **Anatomy of an Expedited/Priority Review**
Moderator: ***Robert "Bob" Pollock, RPh, MS***
Senior Advisor, Outside Director to the Board
Lachman Consultant 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 & CEO, Lachman Consultant Services, Inc.
LCDR Mahesh Ramanadham, PharmD, MBA (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-C / White Oak

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

GDUFA II Implementation – Industry Negotiators Perspective on the First Month Salon D-E	Highlights from FDA-USP Workshop on Excipients Salon H	The Path to Bioequivalence – Great Progress, Great Opportunities Salon G
Moderator: ***Marcy Macdonald, RAC*** Vice President, Regulatory Affairs, Impax Laboratories ***Kiran Krishnan, PhD*** Senior Vice President, Global Regulatory Affairs, Apotex Corp. ***Lisa Parks, RPh*** Vice President, Sciences & Regulatory Affairs, AAM ***Molly Rapp*** Vice President, Regulatory Affairs US Innovation and Development, Generics and Standard Solutions Fresenius Kabi USA, LLC ***Scott Tomsky, MS, BS*** Vice President, Regulatory Affairs, Generics North America Teva Pharmaceuticals	Moderator: ***Ravi Harapanhalli, PhD*** Senior Vice President, Global Regulatory Affairs Amneal Pharmaceuticals ***John Giannone*** Senior Director, Excipients, Strategic Marketing and Program Operations USP ***Catherine Sheehan, MS*** Senior Director Science-Excipients, USP	Moderator: ***Dominique Kendrick, RPh, MBA, RAC*** President, EverestGreen Partners, Inc. ***Charles DiLiberti*** President Montclair Bioequivalence Services, LLC ***Keith Gallicano, PhD*** (panelist) Chief Scientific Officer, Novum Pharmaceutical Research Services

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**

Complexity of Retention Samples Selection in Non-Traditional Bioequivalence Studies Salon D-E	Drug Product Quality and the Impact of Extractables and Leachables Salon H	Improving Timeliness of ANDA Approval – A CDMO Perspective Salon G	Drug Product Market Supply – Compliance and Challenges Salon F
Moderator: ***Siva Vaithiyalingam, PhD*** Vice President, Regulatory Affairs North America, Cipla LTD ***Nageshwar Thudi, PhD*** Director, Clinical Research and Development, Teva Pharmaceuticals	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	Moderator: ***Mark Hendrickson*** Senior Director, Sciences & Regulatory Affairs, AAM ***L. Lee Karras*** Chief Executive Officer Halo Pharmaceutical ***Karunakar Sukuru, RPh, PhD*** Vice President, Product Development (US&EU), Softgel Technologies, Catalent Pharma Solutions	Moderator: ***Candis Edwards*** Senior Vice President, Regulatory Affairs, Amneal Pharmaceuticals ***Lara Hansen*** Associate Director, Regulatory Affairs, Sandoz Inc.

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