GRx+Biosims

Engineering the Future of Generic + Biosimilar Medicines

September 5-7, 2018 | Baltimore, MD

WEDNESDAY, SEPTEMBER 5, 2018

7:30 a.m.	***Registration***
9:00 a.m. – 9:30 a.m.	**CMS Keynote Address** – Key Ballroom 1-6 ***Seema Verma*** Administrator, Centers for Medicare and Medicaid Services
9:30 a.m. – 10:00 a.m.	**Deputy Commissioner for Policy, Legislation and International Affairs Keynote Address** ***Anna Abram*** Deputy Commissioner for Policy, Planning, Legislation and Analysis, FDA
10:00 a.m. – 10:15 a.m.	***Networking Break*** – Key South Foyer
10:15 a.m. – 11:00 a.m.	**Rising Drug Prices and Sustainable Competition** – Key Ballroom 1-6 The Trump Administration is taking steps to address rising prescription drug costs that include promoting competition in the pharmaceutical market from generic and biosimilar medicines. Yet getting generics and biosimilars to the market, and keeping them on the market, remain serious challenges. This session will discuss recent policymaker initiatives to lower prices and the opportunities and challenges for our industry in the current environment. ***John O'Brien, PharmD*** Advisor to the Secretary, Deputy Assistant Secretary (Health Policy), Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services ***Daniel Best*** Senior Advisor to the Secretary for Drug Pricing Reform Department of Health and Human Services
11:00 a.m. – 11:30 a.m.	**CDER Keynote Address** ***Patrizia Cavazzoni, M.D.*** Deputy Director for Operations, CDER, FDA
11:30 a.m. – 12:00 p.m.	**State of the Industry Address** ***Chester "Chip" Davis, Jr., JD*** President & CEO, AAM

12:00 p.m. – 1:30 p.m. *Networking Luncheon*

GRx+Biosims Breakout Sessions:

1:30 p.m. – 3:00 p.m.

Global Experience with Biosimilars – Key Ballroom 8

Biosimilars have been in use globally for more than a decade. Learn more about the latest data supporting their safety and efficacy as well as the significant role biosimilars have played in increasing patient access to life-altering medicines and ensuring health system viability through savings.

Moderator: ***Terri Stewart***
Senior Advisor, Abraxeolus Consulting
Kyung-Ah Kim
Vice President of Biosimilar Development, Samsung Bioepsis
Hillel Cohen, Ph.D.
Executive Director, Scientific Affairs, Sandoz Biopharmaceuticals
Marc-Alexander Mahl, M.D.
Executive Vice President, Business Unit Generic Drugs, Fresenius Kabi
President, Medicines for Europe

1:30 p.m. – 3:00 p.m.

Data Integrity – Key Ballroom 11-12

This presentation will discussion data integrity across the life cycle of product management from development to commercialization and post market surveillance. The discussion will also highlight the controls and cultural aspects as well as current trends.

Moderator: ***Frances Zipp***
President & CEO, Lachman Consultant Services, Inc.
Derek Glover
Head of Global Quality Systems and Compliance, Mylan Pharmaceuticals Inc.
Sarah Barkow, PhD
Lead Consumer Safety Officer, Office of Manufacturing Quality, Office of Compliance, FDA
Howard Sklamberg, JD
Partner, Akin Gump Strauss Hauer & Feld LLP
Carmelo Rosa, BS. MS, PsyD
Director, Division of Drug, Quality I, Office of Compliance, FDA

1:30 p.m. – 3:00 p.m.

Perspectives on the Future of ICH– Key Ballroom 9-10

ICH has reorganized itself over the past 3 years to better accommodate and represent the interests of all the global drug regulatory authorities and sectors of the pharmaceutical industry. As an outcome of this reorganization the generic and biosimilar industries are now represented in the ICH Management Committee by the International Generic and Biosimilar Medicines Association (IGBA). IGBA is composed of the major generic and biosimilar associations from around the world. AAM is one of the founding members of IGBA.

During this meeting we will hear from a panel consisting of individuals who are intimately involved in the operation of ICH.

Moderator: ***Nicholas Cappuccino, Jr., PhD***
Vice-President, Head of Quality and Scientific Affairs, Dr. Reddy's Laboratories, Inc.
Chair, Science Committee IGBA
C. Michelle Limoli, PharmD
Senior International Health Science Advisor, CBER, FDA
Theresa Mullin, PhD
Associate Director for Strategic Initiatives, CDER, FDA
Jerry Stewart, JD, MS, RPh
Deputy Vice President, Scientific and Regulatory Advocacy PhRMA

1:30 p.m. – 3:00 p.m.

Drug Pricing and Update on State Legal Issues – Peale (1st level)

As numerous states wrestle with the issue of drug pricing and our nation's opioid crisis, several have considered or enacted legislation that would affect generics and biosimilars. This panel will provide an overview of new state law proposals as well as litigation arguments against some of these proposals, including those in Maryland, California and Nevada.

Jonathan Janow, JD
Partner, Kirkland & Ellis LLP
Matthew Rowen, JD
Associate, Kirkland & Ellis LLP
Stephanie Trunk, JD
Partner, Arent Fox LLP

1:30p.m. – 2:30 p.m.

USP Stakeholder Engagement Through Monograph Development – Douglass (3rd level)

This session will serve to raise awareness about the working relationship between USP, FDA, and industry, specifically how USP monographs are developed and the importance of the exchange of information, engagement of stakeholders, as well as USP collaborations with the agency beyond monograph development.

Jen Devine, JD
Vice President, Global Legal Affairs, USP
Elizabeth Miller, PharmD
Vice President, U.S. Regulatory Affairs and Public Policy, USP

3:00p.m. – 3:30 p.m. ***Networking Break***

GRx+Biosims Breakout Sessions:

3:30 p.m. – 4:30 p.m.

Biosimilars Regulatory Expectations & Experiences – Key Ballroom 8

Panel discussion of recent FDA guidance's on biosimilars and sponsors' experiences working with FDA throughout the approval process.

Michelle Lee-Bourner
Head of Regulatory Affairs – Biologics and Respiratory, Mylan, Inc.
Gillian Woollett, MA, DPhil
Senior Vice President, Avalere Health LLC

3:30 p.m. – 5:00 p.m.

What's Important to Consider When Developing a Complex Generic Drug? – Key Ballroom 11-12

FDA has provided drug manufacturers a number of tools to assist in the development of complex generic drugs that will provide high-quality, lower-cost alternatives for patients. As manufacturers decide on strategies to develop these complex, generic products they need to consider a number of aspects including current guidance and expectations from the FDA, enhanced communication opportunities, ensuring facility inspection readiness, and developing innovative characterization techniques.

This session will prime the discussion on what aspects are important to consider when developing a generic product and allow for participants to provide feedback on what questions and challenges they may be facing when developing these types of products.
Moderator: Robert Iser, MS
Vice President, PAREXEL Consulting
Robert Lionberger, PhD
Director, Office of Research Standards (ORS), OGD, FDA
Kiran Krishnan, PhD
Senior Vice President Global Regulatory Affairs, Apotex Inc.
Marcy MacDonald, RAC
Vice President, Regulatory Affairs, Amneal Pharmaceuticals
Wayne Talton
Head of Global Regulatory Affairs, Mylan Inc.
Scott Tomsky, MS, BS
Vice President, Generics Regulatory Affairs, North America, Teva Pharmaceuticals
Molly Ventrelli
Vice President, Regulatory Affairs, Fresenius Kabi USA, LLC

3:30 p.m. – 4:30 p.m.

Prescription Drug & Opioid Abuse – Prevention Education – Key Ballroom 9-10

The White House has launched its own "engage and enrage" strategy to stem the opioid crisis among young people. AAM and others in the Rx supply chain, including distributors and major retail pharmacies, have teamed up with education technology leader EVERFI, Inc. to provide a digital and evidence-based public health approach to empower students across the nation with skills to make healthy choices about prescription drug use, storage and disposal. Learn about the Prescription Drug Safety Network, data collected to date and ways to become involved. This session is open to all.

Melissa Leonsis
Director of Global Partnerships, EverFi, Inc.
Dan Zapp, PhD
Senior Director of Research, EverFi, Inc.
Kimberly Timpf, MEd
Senior Director, Prevention Education, EverFi, Inc.

4:00 p.m. – 5:00 p.m. **AAM Law Committee Meeting** – Paca (3rd Level)
(Invitation only)

5:00 p.m. – 6:30 p.m. ***Welcome Reception*** – Key Ballroom South Foyer

THURSDAY, SEPTEMBER 6, 2018

8:30 a.m. – 9:00 a.m. **OPQ Keynote Address** – Key Ballroom 1-6
Ashley Boam
Director, Office of Policy, OPQ, CDER, FDA

9:00 a.m. – 10:00 a.m. **Discussion with Biosimilars Industry Leaders**
Moderator: ***Stanton Mehr***
Director of Content, Biosimilars Review & Report
Gary Deeb
Senior Vice President – Global Licensing and Business Development, Lupin
Chrys Kokino
Head of Biologics - North America, Mylan Inc.
Mike Woolcock
Senior Vice President, Commercial Operations, Apobiologix

10:00 a.m. – 10:30 a.m. ***Networking Break*** – Key Ballroom South Foyer

10:30 a.m. – 11:30 a.m. **Successfully Managing Priority Generic Submissions** – Key Ballroom 1-6
FDA has provided drug manufacturers additional options for the development of priority generic drugs in order to meet needs of patients and caregivers in a timelier manner. As manufacturers decide on strategies to develop priority generic products they will need to understand what the current FDA expectations mean to their development program, including the submission of pre-submission facility correspondences. This session will offer a view-point of what is important to consider when deciding to utilize the priority pathway for the development of generic products and will also allow for alternate viewpoints from the audience on lessons learned related to submission, review and approval of priority products.

Moderator: ***Robert Iser, MS***
Vice President, PAREXEL Consulting
Kiran Krishnan, PhD
Senior Vice President Global Regulatory Affairs, Apotex Inc.
Aloka Srinivasan, PhD
Vice President, Regulatory Practice, Lachman Consultant Services, Inc.
Scott Tomsky, MS, BS
VP, Generics Regulatory Affairs, North America at Teva Pharmaceuticals

11:30 a.m. – 12:30 p.m.

Breaking Through on Biosimilars: Market Development & Access

Discussion about reasons for the delta between FDA approval of biosimilars and launches and how to get more biosimilars in the hands of patients. Specifically, this discussion will address exclusionary contracting practices, education and misinformation of stakeholders, and challenges related to overcoming "patent thickets".

Moderator: ***Alex Brill***
CEO, Matrix Global Advisors
Bruce Leicher, JD
General Counsel, Senior Vice President and Secretary, Momenta Pharmaceuticals Inc.
Chrys Kokino
Head of Biologics - North America, Mylan Inc.

12:30 p.m. – 2:00 p.m. ***Networking Luncheon*** – Key Ballroom 1-6

GRx+Biosims Breakout Sessions:

2:00 p.m. – 3:00 p.m.

FDA's Center for Drug Evaluation and Research: Informatics Initiatives to Modernize the Generic Drug Review Process

Key Ballroom 8

In October 2017 the CDER Direct NextGen Collaboration Portal (Portal) was extended to accept submission of pre-ANDA meeting requests which were established as part of GDUFA II legislation. The Portal represents a fundamental paradigm shift in how FDA and Industry collaborate, as potential applicants are able to establish managed accounts and submit pre-validated information in a highly structured manner, then access pertinent information and regulatory decisions in the Portal's intuitive user interface. The Office of Business Informatics envisions new opportunities to expand use of the Portal and further streamline interactions between FDA and our industry partners.

CDER's Office of Business Informatics will provide updates on the level of industry compliance with eCTD requirements, analyses of clinical and analytical study submission data, and known challenges and expectations for information related to bioequivalence study sites and manufacturing facilities referenced in ANDA applications. Applicants are expected to use this information to improve the quality of data being submitted and avoid potential delays in application review.

Jonathan Resnick
Project Management Officer, Division of Data Management Services and Solutions, OBI, OSP, CDER, FDA
Jonathan Rappaport, MBA, PMP
Director, Division of Regulatory Review and Drug Safety Services and Solutions, OBI, OSP, CDER, FDA

2:00 p.m. – 3:00 p.m.

Biosimilars Reimbursement – Key Ballroom 11-12

Panel discussion on the treatment of biosimilars throughout federal programs and an update on recent revisions to reimbursement policy and the impact those changes will have on the development of the US biosimilars market.

The discussion will also include additional changes to current policy that could help spur biosimilar adoption and utilization.

Moderator: ***Craig Burton***
Vice President, Policy, AAM
Molly Burich, MS
Director, Public Policy: Biosimilars and Reimbursement, Boehringer Ingelheim Pharmaceuticals, Inc.
Melissa Andel, MPP
Vice President of Health Policy, Applied Policy

2:00 p.m. – 3:00 p.m.

Legal Issues in GDUFA, FDARA, and Administration Proposals – Peale (1st Level)

FDA's continued modernization of the generic drug approval process gives rise to new legal considerations. This session will examine recent statutory changes as a result of FDARA as well as legal issues that arise in FDA inspections, including data integrity issues.

Kurt Karst, JD
Director, Hyman, Phelps & McNamara, P.C.
Mark Schwartz, JD
Director, Hyman, Phelps & McNamara, P.C.

2:00 p.m. – 3:00 p.m.

FDA Hiring and Retention Initiative – An Overview of the Agency's HR Process – Johnson (1st Level)

This presentation will provide an overview of the current hiring and retention initiatives at the agency, and the effect on the success of the user fee programs. The speaker will provide insight into the CDER and CBER Hiring Pilot to facilitate the agency's ability to get from current to future state.

Melanie Keller
Acting Associate Commissioner for Scientific and Clinical Recruitment, Office of Medical Products and Tobacco, FDA

3:00 p.m. – 3:30 p.m. ***Networking Break*** – Key Ballroom South

GRx+Biosims Breakout Sessions:

3:30 p.m. – 4:30 p.m.

The Role of Variability in Biosimilar Development – Key Ballroom 11-12

Speaker presentation to help biosimilar developers better understand how variability in biologics manufacturing affects demonstrating similarity to a reference project.

Hillel Cohen, Ph.D.
Executive Director, Scientific Affairs, Sandoz Biopharmaceuticals

3:30 p.m. – 4:30 p.m.

Update on GDUFA and BsUFA User Fees – Key Ballroom 8

This presentation will provide an overview of the progress with the implementation of the first year of GDUFA II and BsUFA II user fees. The speaker will recap how the user fee structure for both GDUFA II and BsUFA II changed from that of GDUFA I and BsUFA I, provide an update on the programs fee implementation at this current time and leave you with useful reminders about user fee-related deadlines.

Donal Parks, MBA, MPM
Director, Division of User Fee Management and Budget Formulation Office of Management, FDA
Beena Alex, MPH (Panelist)
Lead Management Analyst, Division of User Fee Management and Budget Formulation, Office of Management (OM), CDER, FDA
LCDR Evelyn Hong, Pharm.D. (Panelist)
Program Manager, Division of User Fee Management and Budget Formulation, OM, CDER, FDA (Confirmed Panelist)
Timothy Jetton, RPh, RAC (Panelist)
Program Management Officer, Division of User Fee Management and Budget Formulation, OM, CDER, FDA (Confirmed Panelist)
Gisa Perez, MBA (Panelist)
Branch Chief, Division of User Fee Management and Budget Formulation, OM, CDER, FDA
LCDR Hanah Pham, PharmD (Panelist)
Facilities Team Lead, Generics Branch, Division of User Fee Management and Budget Formulation, OM, CDER, FDA

3:30 p.m. – 4:30 p.m.

Emerging Legal Issues in IP and Paragraph IV Litigation – Peale (1st Floor)

Hear from practitioners about the latest trends in Paragraph IV and IP litigation. In particular, we will consider changes in the IPR process in the wake of recent Supreme Court rulings and potential legislative changes to IPR.

Frederick Ball, JD
Partner, Duane Morris LLP
Patrick Gallagher, Ph.D.
Partner, Duane Morris LLP

3:30 p.m. – 4:30 p.m.

Uninsured, Underinsured and Disaster Access – Direct Relief – Johnson (1st Floor)

Houston. Puerto Rico. Syria. In natural and man-made disasters, generics and biosimilars can provide relief to patients who cannot access needed meds. Whether a population here or abroad is in a chronic or acute crisis, Direct Relief provides a way for your company to serve the underserved. The organization is recognized as a Verified-Accredited Wholesale Distributor (VAWD) of pharmaceuticals by the National Association of Boards of Pharmacy (NABP). Learn about the ways you and your company can partner with non-profit NGOs, like Direct Relief, to provide humanitarian assistance. This session is open to all.

Moderator: ***Thomas Roane***
Director of Strategic Initiatives, Direct Relief
Amalia Adler-Waxman
Vice President, Global Head Social Impact and Responsibility, Teva Pharmaceuticals
Malvise A. Scott
Senior Vice President, Partnership and Resource Development, National Association of Community Health Centers
Damon Taugher
Director of US Programs, Direct Relief

3:30 p.m. – 4:30 p.m.

USP Pending Monograph Process – Douglass (3rd Floor)

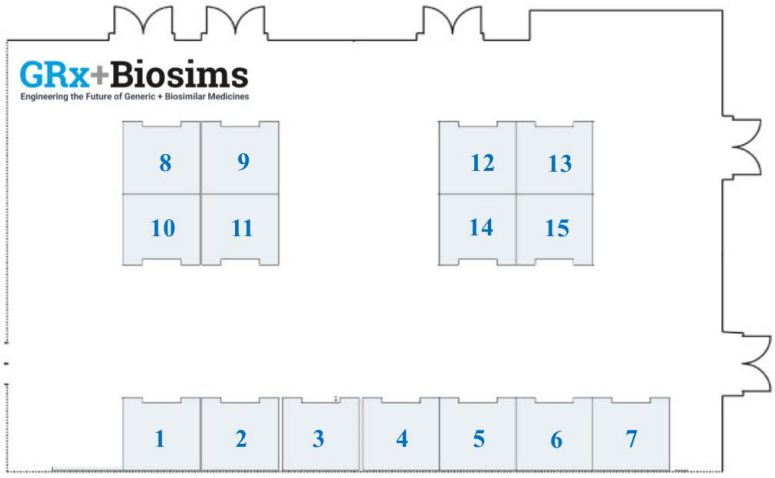
This session will provide an overview of the USP Pending Monograph Program (PMP). The USP PMP allows for development of monographs or monograph revisions for articles awaiting approval by FDA, and permits publication of these proposals in the Pharmacopeial Forum (PF) for notice and comment when required. The PMP can be utilized in situations in which USP does not yet have a monograph for a drug, or for which there is an existing monograph with requirements that are not met by a potential product under review by FDA. It allows the new or revised monograph to become official more rapidly than would be possible if development began only after final FDA approval.

Elizabeth Bladen, M.A., M.L.S., M.S.
Documentary Standards Operations Program Manager, USP

3:30 p.m. – 5:30 p.m.

GRx + Biosims Exposition – Key Ballroom 7, 9, 10

The GRx+Biosims Expo session is an interactive knowledge sharing session that brings together multiple levels of scientific disciplines from diverse sectors, industry, academia and agency. The expo is geared toward facilitating one-on-one interaction among these sectors to increase understanding on a scientific level.



1. **Office of Regulatory Affairs**
2. **Discovering FDA Expectations Through Deficiency**
3. **Road to One Cycle Reviews**
4. **USP Strategies and Perspectives on Excipient Quality**
5. **Impact of the Current Controlled Correspondence Practices and Increasing Access**
6. **Drug Device Combination Products: How Similar Is Similar-Challenges Industry is Having**
7. **Efficient Harmonization: Moving Toward a Global Reference Product**
8. **Office of Business Informatics**
9. **Facility Complexities Under GDUFA II**
10. **Roadmap to Paradise- A Seamless Journey from Product Development to Launch**
11. **Drug Shortage Staff**
12. **Biosimilars – Complexities in Global Development Within a Dynamic Regulatory Environment**
13. **Generic Opioid Abuse Deterrent Formulations — The Right Study Design for the Right ADF**
14. **& 15. Office of Management BSUFA & GDUFA**

see last page for GRx+Biosims Exposition Participants*

3:30 p.m. – 5:30 p.m.

Biosimilars Council Meeting – Paca (3rd Floor)

(By Invitation Only)

4:30 p.m. – 5:30 p.m.

Amplify our Voice – Communications Task Force Meeting – Johnson (1st Floor)

The AAM Communications Task Force is a peer-driven committee that meets regularly by phone and occasionally in person to understand how best to position our generics and biosimilars industry for success with critical stakeholder groups, including patients, providers, the media and policymakers. We ensure that everyone has the communications tools and key messages, like the industry's value proposition, necessary to amplify our industry's voice to these audiences. Education campaigns to improve understanding of biosimilars; appreciation for generic safety, efficacy and savings; and support for our advocacy are all in the purview of the Task Force. Your ideas and participation are welcome. Open to all communication and marketing professionals at AAM member companies.

5:30 p.m. – 6:30 p.m.

Networking Reception – Key Ballroom South

6:30 p.m. – 9:30 p.m.

Dinner & Entertainment – Key Ballroom 1-6

FRIDAY, SEPTEMBER 7, 2018

8:30 a.m. – 9:00 a.m.

OGD Updates – Key Ballroom 1-6

Kathleen Uhl, M.D.
Director, Office of Generic Drugs (OGD), Food and Drug Administration

9:00 a.m. – 10:30 a.m.

Bridging the Education Gap: Accelerating the Understanding of Biosimilars to Optimize Patient Care

Panel discussion that includes representatives from various healthcare stakeholder organizations sharing their perspectives on the evolution of biosimilar education as well as current challenges in the space.

Moderator: ***Christine Simmon***
Senior Vice President, Policy & Strategic Alliance, AAM
Executive Director, Biosimilars Council

Leah Christl, PhD
Associate Director for Therapeutic Biologics
Director, OND Therapeutic Biologics and Biosimilars Staff (TBBS)
Office of New Drugs, CDER, FDA

Gary H. Lyman, MD, MPH, FRCP, FASCO
Chair, Biosimilars Work Group
American Society of Clinical Oncology
Co-Director, Hutchinson Institute for Cancer Outcomes Research
Fred Hutchinson Cancer Research Center
Professor of Medicine, Public Health, and Pharmacy,
University of Washington School of Medicine

Stacie Maass, BSPharm, JD
Senior Vice President, Pharmacy Practice and Government Affairs, American Pharmacists Association

Louis Tharp
Co-Founder and Executive Director, Global Healthy Living Foundation

10:30 a.m. – 11:00 a.m. ***Networking Break*** – Key Ballroom South

GRx+Biosims Breakout Sessions:

11:00 a.m. – 12:00 p.m.

Drug Competition Action Plan and Biosimilars Action Plan (BAP) – Key Ballroom 1-6

This presentation will provide an overview of the commissioner's Drug Competition Action Plan and Biosimilars Action Plan (BAP) and highlight the key success as well as challenges of implementation.

Leah Christl, PhD
Associate Director for Therapeutic Biologics
Director, OND Therapeutic Biologics and Biosimilars Staff (TBBS), Office of New Drugs, CDER, FDA

Maryll Toufanian, JD
Director, Office of Generic Drug Policy, OGD, FDA

11:00 a.m. – 12:00 p.m.

Old, New, and Future Challenges in Bioequivalence – Key Ballroom 8

GDUFA funding and research have fueled tremendous advances in bioequivalence (BE) regulations, which, in turn, have greatly facilitated generic drug development and approvals. However, the rapid-fire issuance of new BE guidances has also led to new BE issues that adversely affect generic drug development and approvals in unintended ways. These, together with lingering BE issues that FDA has not yet addressed, and emerging BE issues just crossing the horizon, will be discussed by our panel of seasoned industry and CRO experts, with, we expect, lively audience participation.

Moderator: ***Charlie DiLiberti***
President, Montclair Bioequivalence Services LLC
Keith Gallicano, PhD
Chief Scientific Officer, Novum Pharmaceutical Research Services
Russ Rackley, PhD
Head, Global Pharmacokinetics/Drug Metabolism, Mylan Inc.
Nageshwar Thudi, PhD
Senior Director, Clinical End Point Studies – Global, Teva Pharmaceuticals
William Zarycranski, PharmD
Director Clinical Development – Early Phase, Sandoz Inc. A Novartis Company

11:00 a.m. – 12:00 p.m.

The 5 Year Financial Plan for GDUFA and BsUFA – Key Ballroom 11-12

One reporting requirement for FDA that resulted in the reauthorization of the BsUFA and GDUFA user fee programs is that FDA will publish a five-year financial plan no later than the second quarter of Fiscal Year 2018. The speaker will provide an overview of what the reports captures, how the information will be used by the Agency and the impact it will have on the user fee programs, highlighting the similarities and differences between the two programs.

Jay Tyler
Chief Financial Officer, FDA

12:00 p.m. – 1:30 p.m. ***Networking Luncheon*** – Key Ballroom 1-6

12:00 p.m. – 1:30 p.m. ***Biosimilars Council Luncheon***
(Invitation only)

GRx+Biosims Breakout Sessions:

1:30 p.m. – 2:30 p.m.

Biosimilars at the Bar – Key Ballroom 11-12

An update on BPCIA Litigation and the Patent Dance as well as current obstacles in the legal realm concerning bringing biosimilars to market.

Elaine Herrmann Blais, JD
Partner, Goodwin Procter LLP
Scott Lassman, JD, MA
Partner, Goodwin Procter LLP

1:30 p.m. – 2:30 p.m.

Telling Your Company's Story – Johnson (1st Floor)

So many of the challenges we face today come from a lack of understanding of what makes our industry different and special. Fortunately, generic and biosimilar drug makers have great stories to tell. The general lack of information plus some misinformation about our industry can be reversed by each of us telling the story of our companies, our products, our teams and our work for our communities. With so many tools and channels available today, from video to social media to infographics, anyone and everyone can and should be a storyteller. Come learn the essentials to enhance our collective advocacy.

Alex Conant
Partner, Firehouse Strategies
Dave Vermillion
Senior Strategist & Managing Director, Firehouse Strategies

1:30 p.m. – 2:30 p.m.

Serialization for Today and Tomorrow – Key Ballroom 8

The implementation of serialized products for The Drug Supply Chain Security Act (DSCSA) brings operational, regulatory and business challenges for every company in the U.S. market. Subject- matter experts from industry will discuss the current state of implementation and what they expect to see for the final requirements to be completed in 2023.

Moderator: ***Mark Hendrickson, MS***
Senior Director, Sciences & Regulatory Affairs, AAM
Mary Anne Anderson
Director, Program Management, Fresenius Kabi USA
Lloyd Mager
Manager Strategic Initiatives Supply Chain Operations, AbbVie Inc.
Brian D. Rezach
Partner, OmniMedia Associates LLC

1:30 p.m. – 2:30 p.m.

GDUFA II Complex Products: Pre-ANDA Meeting Process – Peale (1st Floor)

The Pre-ANDA Program is designed to assist the ANDA sponsor to develop more complete submissions, promote a more efficient and effective ANDA review process, and reduce the number of review cycles and facilitated approval of complex generic products. The program features product development, pre-submission and mid-cycle review meetings to help clarify regulatory expectations early in product development and during application review. This session will provide insight into how FDA and industry are managing the new program. It will also provide updates to key areas, identify challenges and helpful hints.

Kris Andre, MS
Associate Director, Regulatory Affairs, ORS, OGD, FDA
Robert Lionberger, PhD
Director, Office of Research Standards (ORS), OGD, FDA

1:30 p.m. – 2:30 p.m.

Modernization of Organic Impurities Testing in USP Monographs – Douglass (3rd level)

"Impurities" in drug substance (DS) and drug product (DP) is a CQA in pharmaceutical products because of their potential to affect the safety and efficacy. Impurity measurements and control processes continue to evolve significantly as a result of scientific and technological innovations. These innovations, in combination with advancements in the field of toxicology, have contributed to the evolution of global regulatory standards for control of impurities in drug substances and drug products.

The USP Expert Panel on "Modernization of Organic Impurities Testing in Drug Substances and Drug Products" is in the process of modernizing the USP chapters on organic impurities, <476> Organic Impurities in Drug Substances and Drug Products and <1086> Impurities in Drug Substances and Drug Products.

Antonio Hernandez-Cardoso, MSc
Senior Scientific Liaison, Science-General Chapters, USP

2:30 p.m. ***GRx+Biosims Concludes***

GRx+BIOSIMS EXPOSITION PARTICIPANTS - THURSDAY, SEPTEMBER 6, 2018

Raja Agnihotram, RAC, CCRA, Manager Regulatory Strategy & Science, Sandoz Biopharma
Beena Alex, MPH, Lead Management Analyst, Division of User Fee Management and Budget Formulation, Office of Management (OM), CDER, FDA
Abhijit Barve, M.D., PhD, Head of Global Clinical Research, Mylan, Inc.
Kamilah Blackton, Writer-Editor, Office of Communications and Project Management, ORA, FDA
CAPT Tessa Brown DHSc, MPH, BSN, RN, Deputy Director (Acting), Office of Strategic Programs (OSP), Office of Business Informatics (OBI), CDER, FDA
Germain Bryant, MA, Management Analyst, Division of User Fee Management & Budget Formulation, OM, CDER, FDA
Alonza Cruse, Director, Office of Pharmaceutical Quality Operations, ORA, FDA
Sandra D'Agostino-Ferlisi, Associate Director Regulatory Affairs Intelligence and Training, Apotex Inc.
Aparna Dagar, PhD, RAC, Director, Regulatory Affairs, Fresenius Kabi USA, LLC
Naman Dave, MS, Manager, Regulatory Affairs, Amneal Pharmaceuticals
Joyce Delgaudio, Sr. Director, Regulatory Affairs, Preapproval Generics, Teva Pharmaceuticals USA, Inc.
Nirali Dholaria, MS, Regulatory Associate II, Regulatory Affairs, Amneal Pharmaceuticals
Luis Miguel Faria, Management Analyst, Division of User Fee Management and Budget Formulation, OM, CDER, FDA
John Giannone, Senior Director, Strategic Marketing and Program Operations for Excipients, USP
Madhuri Gupta, RAC-US, Associate Director, Global Regulatory Affairs, Apotex Inc.
Cheryl Hawkins, Management Analyst, Division of User Fee Management and Budget Formulation, OM, CDER, FDA
LCDR Evelyn Hong, PharmD, Program Manager, Division of User Fee Management and Budget Formulation, OM, CDER, FDA
Timothy Jetton, RPh, RAC, Program Management Officer**,** Division of User Fee Management and Budget Formulation**,** OM, CDER, FDA
Christine Kwon, M.E., Supervisory Operations Research Analyst, Division of Regulatory Review and Drug Safety Services & Solutions, Office of Strategic Programs (OSP), Office of Business Informatics (OBI), CDER, FDA
Andrea Miller, JD, Head, Global Research and Development and Regulatory Affairs, Mylan N.V.
Ann Marie Montemurro, Director, Division of Pharmaceutical Quality Programs, Office of Pharmaceutical Quality Operations, ORA, FDA
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