Agenda: Issues and Trends in Regulatory Science

The schedule may be subject to change

DAY 1: MONDAY, MAY 22

Time	Session	Speakers
8:00 – 9:00	**Registration, Breakfast and Networking**	
9:00 – 9:15	**Welcome and Course Overview**	Daniela Drago, PhD *Director Regulatory Affairs Programs, GW* Annette Mollet, PhD *Head of Education and Training, ECPM*
9:15 – 10:00	**The Current Regulatory Environment for Manufacturing and Marketing Drugs and Medical Devices**	John Taylor, JD *President and Principal, Compliance and Regulatory Affairs, Greenleaf Health* *(Formerly Counselor to the FDA Commissioner)*
10:00 – 10:30	**Break**	
10:30 – 11:30	**Does Regulation Enhance or Hinder Innovation?**	Frank F. Weichold, MD, PhD *Director, Critical Path and Regulatory Science Initiatives, ORSI, FDA* Tamima Itani, PhD *Vice President Global Regulatory Policy, Boston Scientific* Tricia DeSantis *Vice President Global Regulatory Policy, Biogen* Jonca Bull, MD *Director, Office of Minority Health, Office of the Commissioner, FDA*
11:30 – 12:15	**The Implications of Clinical Public Heath on Medical Practice**	Lawrence Deyton, MSPH, MD *Senior Associate Dean for Clinical Public Health and Professor of Medicine and Health Policy, GW* *(Formerly Director of the Center for Tobacco Products at FDA)*
12:15 – 1:15	**Lunch**	
1:15 – 2:15	**Challenges and Opportunities for Medical Technology Manufacturers**	Philip J. Phillips *President, Phillips Consulting Group LLC*
2:15 – 2:30	**Break**	

Time	Session	Speakers
2:30 – 3:30	**How to Prepare and Conduct a Successful Meeting with Government Authorities**	Sergio Bonini, MD *Senior Medical Officer, European Medicines Agency (Invited)* Donna Haire *Vice President and Head of Medical Care Global Regulatory Affairs, Bayer HC* Steven Mandernach, JD *Bureau Chief for Food and Consumer Safety, Iowa Department of Inspections and Appeals* Judit Milstein *Chief, Project Management Staff, Office of New Drugs (OND), CDER, FDA (Invited)*
3:30 – 4:00	**Break**	
4:00 – 5:00	**Key Legal and Regulatory Trends Shaping the Medical Device Industry**	Christopher White, JD *Chief Operating Officer and General Counsel, AdvaMed*
5:00 – 5:30	**Interactive Exercise: Sharing Professional Expertise**	Facilitated by Nancy Singer, JD, LLM, RAC, FRAPS *President, Compliance-Alliance*
5:30 – 6:30	**Network Reception**	

DAY 2: TUESDAY, MAY 23

Time	Session
8:00	**Assemble at George Washington University to Take Bus to FDA, White Oak**
9:30	**Arrive White Oak Building 1, Clear Security**
10:00 – 12:00	**Tour of White Oak Campus**
12:15	**Departure to NIH**
12:45	**Arrive at the NIH, Security Screening, Walk to NLM Visitor Center**
12:45 – 1:30	**Lunch in Nobel Laureate Exhibit Hall**
1:30 – 2:30	**Tour at the National Library of Medicine**
2:30 – 2:45	**Travel to the NIH Clinical Center**
2:45 – 4:45	**Combined NIH Overview and Clinical Center Walking Tour**
4:45	**Departure to George Washington University**

DAY 3: WEDNESDAY, MAY 24

Time	Session	Speakers
8:00 – 9:30	**Scientific and Regulatory Writing**	Daniela Drago, PhD *Director Regulatory Affairs Programs, GW*
9:30 – 10:00	**Break**	
10:00 – 10:45	**The New EU Device Regulation: An Overview**	Paul Brooks *Executive Director, RAPS* *(Formerly Senior Vice President, Healthcare Solutions, BSI) (Invited)*
10:45 – 11:45	**China's Own Challenges and Opportunities in Bringing New Medical Devices to the Market.**	Mingdong Zhang, MD, MPH, PhD *Chief Medical Officer and Vice President of Medical and Regulatory Affair, Boston Scientific Corporation China*
11:45 – 12:45	**Lunch**	
12:45 – 1:45	**The Secrets to Effectively Handling FDA Inspections**	Amra Racic, MBA *Principal Regulatory Affairs Policy and Advocacy Specialist, Medtronic* Bob Yocher, FRAPS *Former Senior Vice President Regulatory Affairs, Heartware*
1:45 – 2:30	**Building and Sustaining a Culture of Quality in Tough Economic Times**	John Avellanet *Managing Director & Principal, Cerulean Associates LLC*
2:30 – 3:00	**Break**	
3:00 – 3:45	**Making One Health a Reality — Crossing Bureaucratic Boundaries**	Bernadette Dunham, DVM, PhD *Visiting Professor at Milken Institute School of Public Health, GW* *(Formerly Director of the Center for Veterinary Medicine at FDA)*
3:45 – 4:15	**Accessing Competitive Intelligence under the Freedom of Information Act**	Marlene Bobka *President, FOI Services*
4:15 – 5:30	**Dangerous Documents: Avoiding Land Mines in Your FDA Records and Emails**	Nancy Singer, JD, LLM, RAC, FRAPS *President, Compliance-Alliance*

DAY 4: THURSDAY, MAY 25

Time	Session	Speakers
8:00 – 9:00	**The Changing Climate of Health Care**	Blair Childs *Senior Vice President of Public Affairs, Premier Inc.*
9:00 – 10:00	**Health Policy Trends —What you Need to Know in 2017**	Marcia Nusgart *Executive Director, Alliance of Wound Care Stakeholders*
10:00 – 10:30	**Break**	
10:30 – 11:15	**Drugs and Payers: Pharma Policy**	Tony Barrueta, JD *Senior Vice President Government Relations, Kaiser Permanente (Invited)*
11:15 – 12:00	**How Congress Does Operate?**	Michael Morton, FRAPS *Vice President Corporate Regulatory Affairs, Medtronic*
12:00 – 12:15	**Wrap up and Closing remarks**	Daniela Drago, PhD *Director Regulatory Affairs Programs, GW* Annette Mollet, PhD *Head of Education and Training, ECPM*
12:15 – 1:30	**Lunch on Your Own**	
1:45 – 4:00	**Optional Visit to Congress**	