Agenda: Issues and Trends in Regulatory Science

Please note that the schedule may be subject to change

DAY 1: MONDAY, JULY 11

Time	Session	Speakers
8:00–9:00	**Registration, Breakfast and Networking**	
9:00–9:15	**Welcome and Course Overview**	Daniela Drago, PhD *Director, Clinical & Translational Research and Regulatory Affairs, GW* Annette Mollet, PhD *Head of Education and Training, ECPM*
9:15–10:00	**Advocating for Reasonable Regulations**	Christopher White, JD *Senior Executive Vice President and General Counsel (AdvaMed)*
10:00–10:30	**Interactive Exercise: Sharing Professional Expertise**	Nancy Singer, JD, LLM, RAC, FRAPS *President, Compliance-Alliance*
10:30–11:00	**Break**	
11:00–11:45	**Driving Biomedical Innovation by Advancing Regulatory Science at FDA**	Frank F. Weichold, MD, PhD *Director, Critical Path and Regulatory Science Initiatives, ORSI, FDA*
11:45–1:15	**Lunch**	
1:15–2:00	**Challenges and Opportunities for Pharmaceutical Manufacturers**	Elizabeth Blackwood *Vice President and Chief Quality Officer, Johnson & Johnson Pharmaceuticals*
2:00–2:45	**How to Prepare and Conduct a Successful Meeting with Health Authorities**	Michael Morton, FRAPS *Vice President, Corporate Regulatory Affairs Medtronic* Judit Milstein *Chief, Project Management Staff, Office of New Drugs (OND), CDER, FDA*
2:45-3:15	**Accessing Competitive Intelligence under the Freedom of Information Act**	Marlene Bobka *President at FOI Services, Inc*
3:00–3:15	**Break**	
3:15–4:00	**Why Pharma Companies Should Care About Social Media**	Karla Anderson *Principal, US Pharmaceuticals and Life Sciences, PwC*
4:00–5:00	**Dangerous Documents: Avoiding Land Mines in Your FDA Records and Emails**	Nancy Singer, JD, LLM, RAC, FRAPS *President, Compliance-Alliance*
5:00–6:30	***Network Reception***	

DAY 2: TUESDAY, JULY 12

Time	Session	Speakers
9:30	**Arrive White Oak Building 2, Clear security**	
10:00–10:30	**Overview of Device Regulation**	Kimberly Piermatteo, MHA *LCDR, U.S. Public Health Service, Division of Industry and Consumer Education, Office of Communication and Education,Center for Devices and Radiological Health, FDA*
10:30–11:00	**Overview of Regulatory Science**	Frank F. Weichold, MD, PhD *Director, Critical Path and Regulatory Science Initiatives, ORSI, FDA*
11:00–11:15	**Break**	
11:15– 1:45	**Overview of Minority Health**	Jonca Bull, MD *Director, Office of Minority Health, Office of the Commissioner, FDA*
11:45 -12:15	**Current Issues in Drug Development**	Ameeta Parekh, PhD *Senior Advisor, Scientific Collaborations Office of Translational Sciences, Center for Drug Evaluation and Research, FDA*
12:15	**Departure to NIH**	
12:45	**Arrive at the NIH, Security Screening, Walk to NLM Visitor Center**	Tara Mowery *Branch Chief, NIH Visitor Center & Nobel Laureate Exhibit Hall and Special Events* *National Institutes of Health*
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, JULY 13

Time	Session	Speakers
8:30–9:30	**Regulatory Writing: A Practical Toolkit**	Daniela Drago, PhD *Director, Clinical & Translational Research and Regulatory Affairs, GW* Nancy Singer, JD, LLM, RAC, FRAPS *President, Compliance-Alliance*
9:30–9:45	**Break**	
9:45–10:30	**510(k) Submissions -- What You Don't Know Can Hurt You**	Donna Tillman, PhD, FRAPS *Senior Consultant (Devices), Biologics Consulting Group*
10:30–11:15	**The New EU Device Regulation: A Notified Body Perspective**	Paul Brooks *Senior Vice President, Healthcare Solutions, BSI*
11:15–12:00	**Current Challenges to Medical-Technology Innovation**	Susan Alpert, MD, PhD *Founder and Principal of SFA Consulting*
12:00–1:00	**Lunch**	

Time	Session	Speakers
1:00–1:45	**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* Mark Mansour, JD *Partner, Mayer Brown LLP*
1:45–2:30	**Building and Sustaining a Culture of Quality in Tough Economic Times**	John Avellanet *Managing Director & Principal, Cerulean Associates LLC*
2:30–3:30	**Device Recall Process: Case Studies**	Steve Niedelman *Lead Quality System and Compliance, King & Spalding LLP*
3:30–3:45	**Break**	
3:45–4:45	***Case Study (group work)***	Facilitated by Richard Jones *Vice President General Medicine, inVentiv Health*
4:45–5:15	***Round Table Discussion on Case Study***	

DAY 4: THURSDAY, JULY 14

Time	Session	Speakers
8:30–9:15	**Pharmacoeconomics as a Response to Market Failure: An International Perspective**	Ruth Lopert, MD *Deputy Director, Pharmaceutical Policy and Strategy, Pharmaceuticals and Health Technologies Group, Management Sciences for Health*
9:15–10:00	**The Changing Climate of Health Care: Challenges and Opportunities**	Blair Childs *Senior Vice President of Public Affairs, Premier Inc.*
10:00–10:45	**Making One Health a Reality– Crossing Bureaucratic Boundaries**	Bernadette Dunham, DVM, PhD *Visiting Professor at Milken Institute School of Public Health, GW*
10:45–11:15	**Break**	
11:15–12:00	**Drugs and Payers: Pharma Policy**	Tony Barrueta, JD *Senior Vice President, Government Relations at Kaiser Permanente,*
12:00–12:45	**Trends in Health Care Policy**	Marcia Nusgart *Executive Director at Alliance of Wound Care Stakeholders*
12:45–1:15	**Wrap up and Closing remarks**	Daniela Drago, PhD *Director, Clinical & Translational Research and Regulatory Affairs, GW* Annette Mollet, PhD *Head of Education and Training, ECPM*