AGENDA

Monday, March 8, 2021

Time	Event	Location
AFTERNOON SESSION		
1:00-1:15 p.m.	Welcome and Orientation	**Dean Kelly M. Smith** & **Michael Bartlett**, University of Georgia
1:15-2:00 p.m.	Update from OPQ	**Michael Kopcha,** FDA CDER **(invited)**
2:00-2:30 p.m.	Q&A Session	
2:30-3:15 p.m.	Update from CBER	**Robin Levis**, FDA CBER **(invited)**
3:15-3:45 p.m.	Q&A Session	

Tuesday, March 9, 2021

Time	Event/Topic	Location/Speaker
MORNING SESSION		
8:30-9:15 a.m.	Update from the Office of Regulatory Affairs	**Alonza Cruse**, FDA ORA **(confirmed)**
9:15-9:45 a.m.	Q&A Session	
10:00-10:45 a.m.	GMP Inspection Recognition and Reliance Initiatives	**Mark Birse**, Parexel **(confirmed)**
10:45-11:30 a.m.	Development of a Remote Auditing Program	**Tor Graberg**, AstraZeneca **(confirmed)**
11:30 a.m. - 12:00 p.m.	Q&A Panel	
12:00-1:00 p.m.	Lunch Break	
AFTERNOON SESSION		
1:00-1:45 p.m.	Update from CDER	**Donald Ashley**, FDA CDER **(invited)**
1:45-2:30 p.m.	Health Canada Inspection Trends and Case Studies	**TBD**, Health Canada **(confirmed)**
2:30-3:00 p.m.	Q&A Panel	
3:15-4:00 p.m.	Impact of COVID-19 on the Pharmaceutical Supply Chain	**Robin Kumolyi**, J&J **(confirmed)**

4:00-4:45 p.m.	Sterility Assurance for ATMPs: From isolators back to Grade A	**Crystal Mersh**, QEP **(confirmed)**
4:45-5:15 p.m.	Q&A Panel	

Wednesday, March 10, 2021

Time	Event/Topic	Location/Speaker
MORNING SESSION		
8:15-9:00 a.m.	Case Studies from GMP Inspections	**Ileana Barreto-Petit**, FDA ORA **(confirmed)**
9:00-9:45 a.m.	BREXIT and GMP Inspections	**Tracy Moore**, MHRA **(confirmed)**
9:45-10:15 a.m.	Q&A Panel	
10:30-11:15 a.m.	OTC Monograph Reform in the 2020 CARES Act	**Barbara Kochanowski**, CHPA **(confirmed)**
11:15 a.m. - 12:00 p.m.	GMP Quality Management for OTC Manufacturers	**Jennifer Ahearn**, Eng. Systems, Inc. **(confirmed)**
12:00-12:30 p.m.	Q&A Panel	
	Lunch Break	
AFTERNOON SESSION		
1:00-1:45 p.m.	Post Approval Change Management	**Anil Sawant**, Merck **(confirmed)**
1:45-2:30 p.m.	Combating Counterfeit Pharmaceuticals with Technology	**Ravi Kalyanaraman**, BMS **(confirmed)**
2:30-3:00 p.m.	Q&A Panel	
3:15-4:00 p.m.	A Nitrosamine Case Study	**Beverly Nickerson**, Pfizer **(confirmed)**
4:00-4:45 p.m.	Addressing Nitrosamine Concern in Pharmaceuticals – USP New General Chapter <1469>	**Edmond Biba**, USP **(confirmed)**
4:45-5:15 p.m.	Q&A Panel	

Thursday, March 11, 2021

Time	Event/Topic	Location/Speaker
MORNING SESSION		
8:15-9:00 a.m.	CMC of New Animal Drugs	**Laura Huffman**, FDA CVM **(confirmed)**
9:00-9:45 a.m.	Update on CFR 9 for Vaccine Manufacturing	**Kendall Graber**, USDA CVB **(confirmed)**
9:45-10:15 a.m.	Q&A Panel	
10:30-11:15 a.m.	Development of a COVID-19 Vaccine: GMP Challenges	**TBA**, AstraZeneca **(invited)**
11:15 a.m.-12:00 p.m.	Pharmaceutical Innovation: Challenges & Opportunities from an Industry Perspective	**Socrates Kyritsis**, Novartis **(confirmed)**
12:00-12:30 p.m.	Q&A Panel	
	Lunch Break	
AFTERNOON SESSION		
1:00-1:45 p.m.	Supplier Qualifications – USP General Information Chapter in Development	**Desmond Hunt,** USP **(confirmed)**
1:45-2:30 p.m.	Quality Agreements	**Alan Minsk**, AGG **(confirmed)**
2:30 – 3:00	Q&A Panel	
3:15-4:00 p.m.	OOS Investigation Techniques and Preventive Measures	**James Stumpff**, Parexel **(confirmed)**
4:00-4:45 p.m.	Data Analytics: Holistic approach to implement the digital plant	**Wilfred Mascarenhas**, Eli Lilly **(invited)**
4:45-5:15 p.m.	Q&A Panel	