AGENDA

Monday, March 7, 2022

Time	Event/Topic	Speaker
1:30-1:45 p.m.	Welcome and Orientation	**Dean Kelly M. Smith** & **Michael Bartlett** University of Georgia
1:45-2:30 p.m.	Analytical Procedure Lifecycle approach and QbD principles: Holistic view of analytical procedures performance	**Amanda Mesquita Guiradelli** USP – Brazil (confirmed)
2:30-2:45 p.m.	Q&A Session	

Tuesday, March 8, 2022

Time	Event/Topic	Speaker
	MORNING SESSION	
8:30-9:15 a.m.	Update from the Office of Regulatory Affairs	**Alonza Cruse**, FDA ORA (invited)
9:15-9:45 a.m.	Q&A Session	
9:45-10:30 a.m.	Impact of FDA's Remote Interactive Inspections in Lieu of On-Site Inspections During the COVID Pandemic	**David Chesney**, Chesney Consulting (confirmed)
10:30-11:15 a.m.	Practical Issues and Experiences with Remote Audits and Inspections: An Industry Perspective	**Tor Graberg**, AstraZeneca (confirmed)
11:15-11:45 a.m.	Q&A Panel	
11:45-1:00 p.m.	Lunch Break	
	AFTERNOON SESSION	
1:00-1:45 p.m.	Update from the Office of Manufacturing Quality	**Maan Abduldayem**, FDA CDER (confirmed)
1:45-2:30 p.m.	Update from MHRA	**David Churchward**, MHRA (invited)
2:30-3:00 p.m.	Q&A Panel	
3:00-3:45 p.m.	Elemental Impurities USP <232>	**Kahkashan Zaidi**, USP (confirmed)
3:45-4:30 p.m.	Management Responsibilities for Data Management and Data Governance	**Kir Henrici**, Henrici Group (confirmed)
4:30-5:00 p.m.	Q&A Panel	

Wednesday, March 9, 2022

Time	Event/Topic	Speaker
MORNING SESSION		
8:15-9:00 a.m.	Case Studies from GMP Inspections	**Ileana Barreto-Pettit**, FDA, ORA (invited)
9:00-9:45 a.m.	Update from Health Canada	**TBD**, Health Canada (invited)
9:45-10:15 a.m.	Q&A Panel	
10:15-11:00 a.m.	Forensic Data Integrity Audits	**Brian Duncan**, Quality Executive Partners (confirmed)
11:00 a.m. - 11:45 p.m.	Handling Investigations with Data Integrity Concerns	**Peter Baker**, Green Mountain Quality Assurance (confirmed)
11:45-12:15 p.m.	Q&A Panel	
12:15-1:00 p.m.	Lunch Break	
AFTERNOON SESSION		
1:00-1:45 p.m.	GMP Challenges in Development of a COVID-19 Vaccine	**Richard Tarrant**, Oxford University (confirmed)
1:45-2:30 p.m.	Update from OPPQ	**Ashley Boam**, FDA CDER (confirmed)
2:30-3:00 p.m.	Q&A Panel	
3:00-3:45 p.m.	Legal Considerations for Senior Executives Related to Quality Culture	**Peter Lindsay**, Paul Hastings (confirmed)
3:45-4:30 p.m.	Management's Responsibilities in Establishing a Sustainable Quality Culture	**Frances Marie Zipp**, Lachman Consultant Services (confirmed)
4:30-5:00 p.m.	Q&A Panel	

Thursday, March 10, 2022

Time	Event/Topic	Speaker
MORNING SESSION		
8:15-9:00 a.m.	Quality Metrics and Quality Management Maturity	**Steve Greer**, Genesis Assist (confirmed)
9:00-9:45 a.m.	Update on Quality Metrics	**Hui-I Tom**, FDA CDER (confirmed)
9:45-10:15 a.m.	Q&A Panel	
10:15-11:00 a.m.	QMS for Combination Products for Sites that Produce Both Drugs and Devices	**Jennifer Ahearn**, Engineering Systems (confirmed)
11:00 a.m. - 11:45 p.m.	Business Benefits of Risk-based Computer System Validation	**Mark Matis**, Pharma IT Quality Solutions (confirmed)
11:45-12:15 p.m.	Q&A Panel	
12:15 p.m.	**Conference Adjournment**	
POST-CONFERENCE TUTORIAL		
1:00-2:30 p.m.	Performing Effective Investigations and Root Cause Analysis	**Jennifer Ahearn**, Engineering Systems
2:30-2:45 p.m.	Break	
2:45-4:00 p.m.	Performing Effective Investigations and Root Cause Analysis (continued)	**Jennifer Ahearn**, Engineering Systems
4:00 p.m.	**Post-Conference Adjournment**	
Continuing Education (CE) credit available through this tutorial only.		