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
2:30-3:15 p.m.	Impact and Interpretation of the FDA's Draft Guidance for Inspection of Injectable Products for Visible Particulates	**Steve Langille** ValSource, Inc.
3:15-3:45 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
9:15-9:45 a.m.	Q&A Session	
9:45-10:30 a.m.	Impact of FDA's Remote Interactive Evaluations in Lieu of On-Site Evaluations During the COVID Pandemic	**David Chesney**, Chesney Consulting
10:30-11:15 a.m.	Practical Issues and Experiences with Remote Audits and Inspections: An Industry Perspective	**Tor Graberg**, AstraZeneca
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
1:45-2:30 p.m.	MHRA Update	**Christine (Chris) Gray**, MHRA
2:30-3:00 p.m.	Q&A Panel	
3:00-3:45 p.m.	USP Elemental Impurities Chapters and ICH Q3D	**Kahkashan Zaidi**, USP
3:45-4:30 p.m.	Management Responsibilities for Data Governance and Data Management	**Kir Henrici**, Henrici Group
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
9:00-9:45 a.m.	Update from Health Canada	**Cecilia Bong and Sarah Yu**, Health Canada
9:45-10:15 a.m.	Q&A Panel	
10:15-11:00 a.m.	Advanced Techniques for Evaluating Data Integrity Breach: Using a Forensic Auditing Approach	**Brian Duncan**, Quality Executive Partners
11:00-11:45 a.m.	Handling the Inevitable: GMP Investigations with Data Integrity Concerns	**Peter Baker**, Live Oak Quality Assurance
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.	Finally, a Standard: Microbial Investigations for the Pharmaceutical Industry	**Vanessa Figueroa**, Quality Executive Partners
1:45-2:30 p.m.	Update from the Office of Pharmaceutical Quality	**Ashley Boam**, FDA CDER
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
3:45-4:30 p.m.	Management's Responsibilities in Establishing a Sustainable Quality Culture	**Frances Marie Zipp**, Lachman Consultant Services
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 Maturity – Keys to Quality Excellence	**Steve Greer**, Engineering Systems (ESi)
9:00-9:45 a.m.	FDA Quality Metrics Program: Past, Present, and Future	**Hui-I Tom**, FDA CDER
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
11:00-11:45 a.m.	How to respond to FDA requests for calls or meetings	**Alan Minsk**, Arnall Golden Gregory
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**	

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