

AGENDA

Monday, March 6, 2023

Time	Event/Topic	Location/Speaker
1:30-5:00 p.m.	Registration	Conference Registration Desk
PRE-CONFERENCE TUTORIAL - College of Pharmacy		
2:00-3:15 p.m.	Quality and Compliance Management for Remote (Virtual) Operations	David Chesney , Chesney Consulting (Confirmed)
3:15-3:30 p.m.	Break	
3:30-4:30 p.m.	Quality and Compliance Management for Remote (virtual) Operations (continued)	David Chesney , Chesney Consulting (Confirmed)
5:00-7:00 p.m.	Welcome Reception	Stegman Coliseum (tentative)

Tuesday, March 7, 2023

Time	Event/Topic	Location/Speaker
7:00-8:30 a.m.	Breakfast Buffet	Magnolia Ballroom
7:30-8:30 a.m.	Late Registration	Conference Registration Desk
MORNING SESSION - Magnolia Ballroom		
8:30-8:45 a.m.	Welcome and Orientation	Dean Kelly M. Smith & Michael Bartlett , University of Georgia
8:45-9:30 a.m.	Update from the Office of Regulatory Affairs	Alonza Cruse , FDA ORA (Invited)
9:30-9:45 a.m.	Q&A Panel	
9:45-10:15 a.m.	Networking Break	Magnolia Ballroom
10:15-11:00 a.m.	GMP challenges in 503b compounding pharmacy	Charles Richardson , KRS Biotech (Confirmed)
11:00-11:45 a.m.	Cybersecurity challenges for manufacturing and clinical trials data	Samuel Eubanks , Lonza (Confirmed)
11:45 a.m. - 12:00 p.m.	Q&A Panel	
12:00-1:00 p.m.	Networking Lunch	Magnolia Ballroom

AFTERNOON SESSION - Mahler Auditorium		
1:00-1:45 p.m.	Update from the Office of Pharmaceutical Quality	Ashley Boam , FDA CDER (Invited)
1:45-2:30 p.m.	Keeping pace with innovation and maintaining regulatory oversight	Mark Birse , Paraxel (Confirmed)
2:30-2:45 p.m.	Q&A Panel	
2:45-3:15	Networking Break	Hill Atrium
3:15-4:00 p.m.	Deviation investigations: Human error is not the root cause	James Vesper , Valsource (Confirmed)
4:00-4:45 p.m.	Navigating DSCSA Implementation	Madeleine Giaquinto , Greenleaf Health, Inc. (Confirmed)
4:45-5:00 p.m.	Q&A Panel	
6:30-8:30 p.m.	Dinner “Emergency Preparedness”	Magnolia Ballroom Cham Dallas , University of Georgia

Wednesday, March 8, 2023

Time	Event/Topic	Location/Speaker
7:00-8:15 a.m.	Breakfast Buffet	Magnolia Ballroom
MORNING SESSION - Mahler Auditorium		
8:15-9:00 a.m.	Case Studies from GMP Inspections	Ileana Barreto-Pettit , FDA ORA (Invited)
9:00-9:45 a.m.	Health Canada Inspection Trends and Case Studies	TBD , Health Canada (Invited)
9:45-10:00 a.m.	Q&A Panel	
10:00-10:30 a.m.	Networking Break	Hill Atrium
10:30-11:15 a.m.	Use of new technologies in quality decision making	Fran Zipp , Lachman Consulting Services (Confirmed)
11:15 a.m. - 12:00 p.m.	Science of quality	Jen Ahearn , Eng. Sys. Inc. (Confirmed)
12:00-12:15 p.m.	Q&A Panel	
12:15-1:15 p.m.	Networking Lunch	Magnolia Ballroom

AFTERNOON SESSION - Mahler Auditorium		
1:15-2:00 p.m.	Update from the MHRA	Ewan Norton , MHRA (Invited)
2:00-2:45 p.m.	Update on OOS guidance	Rick Friedman , FDA, CDER (Invited)
2:45-3:00 p.m.	Q&A Panel	
3:00-3:30 p.m.	Networking Break	Hill Atrium
3:30-4:15 p.m.	Policy updates on biologics and cell therapies	Iris Marklein , FDA CBER (Confirmed)
4:15-5:00 p.m.	USP Approach to standards for biologics	Fouad Atouf , USP (Confirmed)
5:00-5:15 p.m.	Q&A Panel	
5:15-6:45 p.m.	Networking Reception, joined by UGA graduate students and postdocs	Hill Atrium
<p>Enjoy dinner in Athens! See http://bit.ly/gmpdinner for inspiration for your night on the town.</p>		

Thursday, March 9, 2023

Time	Event/Topic	Location/Speaker
7:00-8:15 a.m.	Breakfast Buffet	Magnolia Ballroom
MORNING SESSION - Mahler Auditorium		
8:15-9:00 a.m.	Update on QMM	Jennifer Maguire , FDA CDER (Invited)
9:00-9:45 a.m.	Best practices in quality metrics maturity	Steve Greer , Engineering Systems (Confirmed)
9:45-10:00 a.m.	Q&A Panel	
10:00-10:30 a.m.	Networking Break	Hill Atrium
10:30-11:15 a.m.	Legal perspectives on data integrity	Alan Minsk , Arnall, Golden & Gregory (Confirmed)
11:15 a.m. - 12:00 p.m.	Evolution of regulatory surveillance strategies	Sarah Barkow , BMS (Confirmed)
12:00-12:15 p.m.	Q&A Panel	
12:15 p.m.	Conference Adjournment	

POST-CONFERENCE TUTORIAL		
12:15-1:00	Luncheon for Post-Conference Tutorial Participants	Magnolia Ballroom
POST-CONFERENCE TUTORIAL Room YZ – Second Floor (Tentative)		
1:00-2:30 p.m.	Out of Specification Investigations	Jennifer Ahearn, Engineering Systems (Confirmed)
2:30-2:45 p.m.	Networking Break	Kellogg Concourse
2:45-4:00 p.m.	Implementation of new OOS Guidance	Marie Mathews, Engineering Systems (Confirmed)
4:00 p.m.	Post-Conference Adjournment	
<i>Continuing Education (CE) credit available through this tutorial only.</i>		