

AGENDA

Monday, March 4, 2024

Time	Event/Topic	Location/Speaker
3:30-5:00 p.m.	Registration	Conference Registration Desk
5:00-7:00 p.m.	Welcome Reception	Hill Atrium

Tuesday, March 5, 2024

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 – Masters Hall		
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	Hill Atrium
10:15-11:00 a.m.	Case studies in the use of quality analytics	Robert Studt , Janssen (confirmed)
11:00-11:45 a.m.	Quality science to improve drug manufacturing	Thomas Friedli , University of Saint Gallen's (confirmed)
11:45 a.m. - 12:00 p.m.	Q&A Panel	
12:00-1:00 p.m.	Networking Lunch	Magnolia Ballroom
AFTERNOON SESSION – Masters Hall		
1:00-1:45 p.m.	GMP Inspection and Regulatory Updates	TBD, MHRA (invited)
1:45-2:30 p.m.	Updates from USP Micro Expert Committee on Rapid Micro Methods and Bacterial Endotoxin chapters	Huiping Tu and Leslie Furr , USP (confirmed)
2:30-2:45 p.m.	Q&A Panel	
2:45-3:15	Networking Break	Hill Atrium
3:15-4:00 p.m.	Impact of AI in Regulatory, Quality and Manufacturing	Benjamin Stevens , GSK (confirmed)

4:00-4:45 p.m.	Regulatory perspectives on AI	Thomas O’Conner , FDA (invited)
4:45-5:00 p.m.	Q&A Panel	
6:30-8:30 p.m.	Dinner “TBD”	Magnolia Ballroom

Wednesday, March 6, 2024

Time	Event/Topic	Location/Speaker
7:00-8:15 a.m.	Breakfast Buffet	Magnolia Ballroom
MORNING SESSION - Masters Hall		
8:15-9:00 a.m.	Case Studies from GMP Inspections	TBD, FDA (invited)
9:00-9:45 a.m.	Health Canada Inspection Trends and Case Studies	TBD, Health Canada (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.	Data integrity and risk mapping	Kir Henrici , Henrici Group (confirmed)
11:15 a.m. - 12:00 p.m.	Cybersecurity in drug manufacturing	Kurt InAlbon , Lonza (confirmed)
12:00-12:15 p.m.	Q&A Panel	
12:15-1:15 p.m.	Networking Lunch	Magnolia Ballroom
AFTERNOON SESSION - Masters Hall		
1:15-2:00 p.m.	ICH Q12 and Q14 from a regulatory inspection perspective	Ashley Boam , FDA (invited)
2:00-2:45 p.m.	Insights on 483 violations	Ileana Barrato-Pettit , Parexel (confirmed)
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.	Continuous Manufacturing	Eric Jayjock , Vertex (confirmed)
4:15-5:00 p.m.	Aseptic Manufacturing, Annex 1 compliance	Bob Brady , Merck (invited)
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
Enjoy dinner in Athens! See http://bit.ly/gmpdinner for inspiration for your night on the town.		

Thursday, March 7, 2024

Time	Event/Topic	Location/Speaker
7:00-8:15 a.m.	Breakfast Buffet	Magnolia Ballroom
MORNING SESSION - Masters Hall		
8:15-9:00 a.m.	Update from CBER	Iris Marklein , FDA (invited)
9:00-9:45 a.m.	Quality Metrics Maturity	Jennifer Maguire , FDA (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.	TBD	Philip Almeter & Rob Lodder , University of Kentucky (confirmed)
11:15 a.m. - 12:00 p.m.	TBD	Alan Minsk , AGG (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	Kellogg Concourse
POST-CONFERENCE TUTORIAL Room R – Second Floor (Tentative)		
1:00-2:30 p.m.	Effective Remediation Strategies	Jen Ahearn , GMPact
2:30-2:45 p.m.	Networking Break	Kellogg Concourse
2:45-4:00 p.m.	Effective Remediation Strategies	Jen Ahearn , GMPact
4:00 p.m.	Post-Conference Adjournment	