

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 (confirmed)
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.	IMPALA industry consortium: Collaboration and Analytics use cases in R&D quality	Robert Studdt , Janssen (confirmed)
11:00-11:45 a.m.	Building Quality Management 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.	Process capability-based control strategies – A logical next step for ensuring product quality	Eric Jayjock , Vertex (confirmed)
1:45-2:30 p.m.	USP's Evolving position on the use of Endotoxin Testing and Rapid Microbiological Methods	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.	Areas of Consideration for AI in Drug Manufacturing	Thomas O’Conner , FDA (confirmed)
4:45-5:00 p.m.	Q&A Panel	
6:30-8:30 p.m.	Dinner “Drug Shortages”	Magnolia Ballroom Tim Southern , South Dakota Department of Public Health (confirmed)

Wednesday, March 6, 2023

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	Simone Pitts , FDA ORA (invited)
9:00-9:45 a.m.	Health Canada Regulatory Updates	Teresa Forlini , 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 Risk Assessments: Mapping, Mitigation, and Continuous Improvement	Kir Henrici , Henrici Group (confirmed)
11:15 a.m. - 12:00 p.m.	Cybersecurity and Automation in Pharmaceutical 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 : Inspection-Related Considerations	Ashley Boam , FDA (confirmed)
2:00-2:45 p.m.	Insights on 483 violations	Ileana Barreto-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.	GMP Inspection and Regulatory Updates	TBD , MHRA (invited)
4:15-5:00 p.m.	CGT Commercialization challenges and strategies when using CDMOs	Christine Feaster , Quality Executive Partners (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 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.	Predicting GMP Quality Risks at Manufacturing Sites	Jerry Chapman , REDICA Systems (confirmed)
9:00-9:45 a.m.	Update on CDER's Quality Management Maturity Program	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.	Health System Insights for Regulators on Pharmaceutical Quality	Philip Almeter & Rob Lodder , University of Kentucky (confirmed)
11:15 a.m. - 12:00 p.m.	Legal Perspective – Artificial Intelligence in Regulatory Operations	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	Magnolia Ballroom

POST-CONFERENCE TUTORIAL Room YZ – 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	

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