

# AGENDA

Monday, March 4, 2024

Time	Event/Topic	Location/Speaker
4:00-6:00 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
<b>MORNING SESSION – Masters Hall</b>		
8:30-8:45 a.m.	Welcome and Orientation	<b>Dean Kelly M. Smith &amp; Michael Bartlett,</b> University of Georgia
8:45-9:30 a.m.	Update from the Office of Regulatory Affairs	<b>Alonza Cruse,</b> FDA ORA
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	<b>Robert Studdt,</b> Janssen
11:00-11:45 a.m.	Building Quality Management Science to Improve Drug Manufacturing	<b>Thomas Friedli,</b> University of Saint Gallen's
11:45 a.m. - 12:00 p.m.	Q&A Panel	
12:00-1:00 p.m.	Networking Lunch	Magnolia Ballroom
<b>AFTERNOON SESSION – Masters Hall</b>		
1:00-1:45 p.m.	Process capability-based control strategies – A logical next step for ensuring product quality	<b>Eric Jayjock,</b> Vertex
1:45-2:30 p.m.	USP's Evolving position on the use of Endotoxin Testing and Rapid Microbiological Methods	<b>Huiping Tu and Leslie Furr,</b> USP
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	<b>Benjamin Stevens</b> , GSK
4:00-4:45 p.m.	Areas of Consideration for AI in Drug Manufacturing	<b>Thomas O’Conner</b> , FDA
4:45-5:00 p.m.	Q&A Panel	
6:30-8:30 p.m.	Dinner “Drug Shortages”	Magnolia Ballroom <b>Tim Southern</b> , South Dakota Department of Public Health

### Wednesday, March 6, 2023

Time	Event/Topic	Location/Speaker
7:00-8:15 a.m.	Breakfast Buffet	Magnolia Ballroom
<b>MORNING SESSION – Masters Hall</b>		
8:15-9:00 a.m.	Case Studies from GMP Inspections	<b>Simone Pitts</b> , FDA ORA
9:00-9:45 a.m.	Health Canada Regulatory Updates	<b>Teresa Forlini</b> , Health Canada
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	<b>Kir Henrici</b> , Henrici Group
11:15 a.m. - 12:00 p.m.	Cybersecurity and Automation in Pharmaceutical Manufacturing	<b>Kurt In Albon</b> , Lonza
12:00-12:15 p.m.	Q&A Panel	
12:15-1:15 p.m.	Networking Lunch	Magnolia Ballroom
<b>AFTERNOON SESSION – Masters Hall</b>		
1:15-2:00 p.m.	ICH Q12 and Q14: Inspection-Related Considerations	<b>Ashley Boam</b> , FDA
2:00-2:45 p.m.	Insights on FDA 483 Observations	<b>Ileana Barreto-Pettit</b> , Parexel
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.	Responsibilities as a Sponsor of GxP Outsourced Activities	<b>Jen Ahearn</b> , GMPACT
4:15-5:00 p.m.	CGT Commercialization challenges and strategies when using CDMOs	<b>Christine Feaster</b> , Quality Executive Partners
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><b>Enjoy dinner in Athens!</b> See <a href="http://bit.ly/gmpdinner2024">http://bit.ly/gmpdinner2024</a> 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
<b>MORNING SESSION – Masters Hall</b>		
8:15-9:00 a.m.	Predicting GMP Quality Risks at Manufacturing Sites	<b>Jerry Chapman</b> , REDICA Systems
9:00-9:45 a.m.	Update on CDER’s Quality Management Maturity Program	<b>Jennifer Maguire</b> , FDA
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	<b>Philip Almeter &amp; Rob Lodder</b> , University of Kentucky
11:15 a.m. - 12:00 p.m.	Legal Perspective – Artificial Intelligence in Regulatory Operations	<b>Alan Minsk</b> , AGG
12:00-12:15 p.m.	Q&A Panel	
12:15 p.m.	<b>Conference Adjournment</b>	
<b>POST-CONFERENCE TUTORIAL</b>		
12:15-1:00	Luncheon for Post-Conference Tutorial Participants	Kellogg Concourse
<b>POST-CONFERENCE TUTORIAL Room Q – Second Floor</b>		

1:00-2:30 p.m.	Effective Remediation Strategies	<b>Jen Ahearn</b> , GMPact
2:30-2:45 p.m.	Networking Break	Kellogg Concourse
2:45-4:00 p.m.	Effective Remediation Strategies	<b>Jen Ahearn</b> , GMPact
4:00 p.m.	<b>Post-Conference Adjournment</b>	