

AGENDA

Monday, March 3, 2025

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 4, 2025

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 - Mahler 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	LaReese Thomas , FDA Office of Inspections and Investigations (OII) (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.	GMP and AI	Mark Birse , Parexel (confirmed)
11:00-11:45 a.m.	GMP implications for artificial intelligence and machine learning	Jerry Chapman , Redica (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 Hall		
1:00-1:45 p.m.	Toward the global CMC dossier	Lawrence Yu , FDA (confirmed)
1:45-2:30 p.m.	Impact of the Chevron decision on FDA	Alan Minsk , AGG (confirmed)
2:30-2:45 p.m.	Q&A Panel	
2:45-3:15	Networking Break	Hill Atrium

3:15-4:00 p.m.	Update on USP chapter 1078	TBD , USP (confirmed)
4:00-4:45 p.m.	Polyethylene glycol impurities	TBD , USP (confirmed)
4:45-5:00 p.m.	Q&A Panel	
6:30-8:30 p.m.	Dinner	Magnolia Ballroom

Wednesday, March 5, 2025

Time	Event/Topic	Location/Speaker
7:00-8:15 a.m.	Breakfast Buffet	Magnolia Ballroom
MORNING SESSION - Mahler Hall		
8:15-9:00 a.m.	Case Studies from GMP Inspections	Simone Pitts , FDA (confirmed)
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.	TBD	Peter Baker , Live Oak (confirmed)
11:15 a.m. - 12:00 p.m.	Insights into 483s related to EM investigations, visual inspections and smoke studies	Ileana Barrato-Pettit , Parexel (confirmed)
12:00-12:15 p.m.	Q&A Panel	
12:15-1:15 p.m.	Networking Lunch	Magnolia Ballroom
AFTERNOON SESSION - Mahler Hall		
1:15-2:00 p.m.	Update from the Office of Pharmaceutical Quality	Ashley Boam , FDA (confirmed)
2:00-2:45 p.m.	Hot Topics in GxP regulatory intelligence	Sarah Barkow , BMS; Katie Bevard , Eli Lilly; Marie Mathews , Franklin Mathews Group (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.	RWE in post-market surveillance	David Ross , Astra Zeneca (confirmed)
4:15-5:00 p.m.	Use of RWE, AI and digital tools in drug development	Nicole Mahoney , Novartis (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 6, 2025

Time	Event/Topic	Location/Speaker
7:00-8:15 a.m.	Breakfast Buffet	Magnolia Ballroom
MORNING SESSION - Mahler Hall		
8:15-9:00 a.m.	FDA Oversight of Drug Quality – Quality Surveillance	Jennifer Maguire , FDA (confirmed)
9:00-9:45 a.m.	Data integrity by design through automated data capture strategies	Karin Benoit , Eli Lilly (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.	Impact of R&D on quality	Jen Ahearn , GMPact (confirmed)
11:15 a.m. - 12:00 p.m.	MHRA Inspection Trends and Case Studies	Ian Jackson , MHRA (confirmed)
12:00-12:15 p.m.	Q&A Panel	
12:15 p.m.	Conference Adjournment	
12:15-1:00	Networking Luncheon	Magnolia Ballroom
POST-CONFERENCE WORKSHOPS		
CONCURRENT WORKSHOP #1 LOCATION (TBD)		
1:00-2:30 p.m.	Quality Risk Management	Jen Ahearn , GMPact (confirmed)

2:30-2:45 p.m.	Networking Break	Kellogg Concourse
2:45-4:00 p.m.	Quality Risk Management (con't)	Jen Ahearn , GMPact (confirmed)
4:00 p.m.	Post-Conference Adjournment	
CONCURRENT WORKSHOP #2 LOCATION (TBD)		
1:00-2:30 p.m.	Preparation of CMC Dossiers for Multiple Markets	Seppe De Gelas , Hyloris Pharmaceuticals (confirmed)
2:30-2:45 p.m.	Networking Break	Kellogg Concourse
2:45-4:00 p.m.	Preparation of CMC Dossiers for Multiple Markets (con't)	Seppe De Gelas , Hyloris Pharmaceuticals (confirmed)
4:00 p.m.	Post-Conference Adjournment	