

# 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
<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.	Regulatory Landscape for Compounding Pharmacies and Outsourcing Facilities	<b>Jessica McAlister</b> Olympia Pharmaceuticals
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.	The Evolution of AI and its Future in Pharma Quality	<b>Jerry Chapman</b> Redica
11:00-11:45 a.m.	GMP and AI – how Regulatory frameworks keep pace with a rapidly advancing technology	<b>Mark Birse</b> Parexel
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.	Creating & Changing Habits for Excellence	<b>Steve Greer</b> Genesis Assist, LLC
1:45-2:30 p.m.	Some Recent Supreme Court Cases That Might Affect FDA and The Life Science Industry	<b>Alan Minsk</b> AGG
2:30-2:45 p.m.	Q&A Panel	

2:45-3:15	Networking Break	Hill Atrium
3:15-4:00 p.m.	Ensuring Excellence in excipient quality: USP General Chapters Related to GMP	<b>Galina Holloway</b> USP
4:00-4:45 p.m.	Importance of Excipients Quality – USP’s perspective and activities on Diethylene Glycol (DEG)/Ethylene Glycol (EG) testing of high-risk excipients	<b>Jenny Liu</b> USP
4:45-5:00 p.m.	Q&A Panel	
6:30-8:30 p.m.	Dinner  <b>Talk title:</b> Quantum Computing and Its Future	Magnolia Ballroom  <b>Henry F. Schaefer III</b> UGA Center of Computational Quantum Chemistry

### Wednesday, March 5, 2025

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.	FDA’s expectation of ‘vigilant’ oversight: A shift from systems to processes	<b>Peter Baker</b> Live Oak
9:00-9:45 a.m.	Health Canada Inspection Trends and Case Studies	<b>Magda Joseph</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.	GMP & Critical Thinking: are they really compatible?	<b>Peter Baker</b> Live Oak
11:15 a.m. - 12:00 p.m.	What are the FDA’s expectations for GMPs	<b>Ileana Barreto-Pettit</b> Parexel
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.	Applying QRM to the Supply Chain/Drug Shortage Risk – Process, People, and Data	<b>Patrick Day</b> Lachman Consultants
2:00-2:45 p.m.	Hidden Weak Links: Uncovering Supply Chain Blind Spots	<b>Sarah Barkow</b> AstraZeneca <b>Katie Bevard</b> Eli Lilly <b>Marie Mathews</b> Franklin Mathews Group
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 for Regulatory Decision Making	<b>David Ross</b> Astra Zeneca
4:15-4:30 p.m.	Q&A Panel	
4:30-5:30 p.m.	Ask the Experts – Open Mic Session	<b>Jen Ahearn</b> GMPact <b>Sarah Barkow</b> AstraZeneca <b>Steve Greer</b> Genesis Assist, LLC
5:30-7:00 p.m.	Networking Reception, joined by UGA graduate students and postdocs	Hill Atrium
<b>Enjoy dinner in Athens!</b> See <a href="http://bit.ly/gmpdinner">http://bit.ly/gmpdinner</a> 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
<b>MORNING SESSION - Masters Hall</b>		
8:15-9:00 a.m.	Global GMP inspection recognition and reliance	<b>Mark Birse</b> Parexel
9:00-9:45 a.m.	Data integrity by Design through an Automated Data Capture Strategy	<b>Mindi Osgatharp</b> Eli Lilly
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	<b>Jen Ahearn</b> GMPact
11:15 a.m. - 12:00 p.m.	Therapeutic oligonucleotide quality system challenges and their impact on the regulatory sciences	<b>Michael Bartlett</b> University of Georgia
12:00-12:15 p.m.	Q&A Panel	
12:15 p.m.	<b>Conference Adjournment</b>	
12:15-1:00	Networking Luncheon	Magnolia Ballroom
<b>POST-CONFERENCE WORKSHOPS</b>		
<b>CONCURRENT WORKSHOP #1</b> <b>Masters Hall</b>		
1:00-2:30 p.m.	Quality Risk Management	<b>Jen Ahearn</b> GMPact
2:30-2:45 p.m.	Networking Break	Hill Atrium
2:45-4:00 p.m.	Quality Risk Management (con't)	<b>Jen Ahearn</b> GMPact
4:00 p.m.	<b>Post-Conference Adjournment</b>	
<b>CONCURRENT WORKSHOP #2</b> <b>SECOND FLOOR - ROOM Q</b>		
1:00-2:30 p.m.	Preparation of CMC Dossiers for Multiple Regions and Markets	<b>Seppe De Gelas</b> Hyloris Pharmaceuticals
2:30-2:45 p.m.	Networking Break	Kellogg Concourse
2:45-4:00 p.m.	Preparation of CMC Dossiers for Multiple Regions and Markets (con't)	<b>Seppe De Gelas</b> Hyloris Pharmaceuticals
4:00 p.m.	<b>Post-Conference Adjournment</b>	