

AGENDA

Monday, March 2, 2026

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 3, 2026

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		
8:00-8:45 a.m.	Welcoming Remarks	TBD
8:45-9:30 a.m.	Thoughts on the FDA: Past, Present and Future	Robert Califf , Duke University (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.	Update on the Office of Inspections and Investigations	Ivy Sweeney , FDA (invited)
11:00-11:45 a.m.	The FDA is Coming: Are you Ready? A Proactive Approach to 503b Audit Preparedness	Jessica McAlister , Olympia Pharmaceuticals (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 Auditorium		
1:00-1:45 p.m.	The Use of AI in FDA GXP Compliance and Drug Approval	Howard Sklamberg , Arnold & Porter Kaye Scholer (confirmed)
1:45-2:30 p.m.	FDA and non-FDA issues to consider with non-compliance beyond 483s and warning letters	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.	Critical elements of continuous manufacturing/ parametric release	Thomas O’Conner , FDA (invited)
4:00-4:45 p.m.	Aseptic manufacturing without automation: readiness, risks and reality	Jessica Chiaruttini , Valsource (confirmed)
4:45-5:00 p.m.	Q&A Panel	
6:30-8:30 p.m.	Dinner with keynote speaker	Magnolia Ballroom

Wednesday, March 4, 2026

Time	Event/Topic	Location/Speaker
7:00-8:15 a.m.	Breakfast Buffet	Magnolia Ballroom
MORNING SESSION - Mahler Auditorium		
8:15-9:00 a.m.	Case Studies from GMP Inspections	Simone Pitts , FDA (invited)
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.	Data governance & Lean theory: Achieving data integrity through process excellence	Peter Baker , Live Oak (confirmed)
11:15 a.m. - 12:00 p.m.	When Risk is Ignored: GMP Inspection Pitfalls and Compliance Impace	Ileana Barreto-Pettit , Capitana Audit Solutions (confirmed)
12:00-12:15 p.m.	Q&A Panel	
12:15-1:15 p.m.	Networking Lunch	Magnolia Ballroom
AFTERNOON SESSION - Mahler Auditorium		
1:15-2:00 p.m.	Update from the Office of Pharmaceutical Quality	Ashley Boam , FDA (invited)
2:00-2:45 p.m.	Hot Topics in GxP regulatory intelligence	
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.	Quality requirements for Ophthalmic Products	Margareth Marques , USP (confirmed)
4:15-5:00 p.m.	Quality Matters: The Importance of Particulate Matter in Pharmaceutical Quality	Desmond Hunt , USP (confirmed)
5:00-5:15 p.m.	Q&A Panel	
5:30-6:15 p.m.	Shuttle Service to Sanford Stadium <ul style="list-style-type: none">- Destination: West End Zone Lounge, Sanford Stadium- Pick-up: Outside the Georgia Center Hotel Lobby Entrance	
6:00-7:30 p.m.	Celebration Reception <ul style="list-style-type: none">- Location: West End Zone Lounge, Sanford Stadium- Joined by UGA graduate students and postdocs	
7:30-8:00 p.m.	Return Shuttle Service to the Georgia Center <ul style="list-style-type: none">- Pick-up: Sanford Stadium West End Zone Entrance – Bridge Level <p>*NOTE: Shuttle service will be available continuously from 5:30-8:00 p.m.</p>	
Enjoy dinner in Athens! See https://www.visitathensga.com/ for inspiration for your night on the town.		

Thursday, March 5, 2026

Time	Event/Topic	Location/Speaker
7:00-8:15 a.m.	Breakfast Buffet	Magnolia Ballroom
MORNING SESSION - Mahler Auditorium		
8:15-9:00 a.m.	Update on the FDA's Quality Management Maturity (QMM) initiative: update and next steps – Quality Culture	Nyrma CruzRuiz , FDA (confirmed)
9:00-9:45 a.m.	MHRA Inspection Trends and Case Studies	TBD , MHRA (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.	Autologous versus allogeneic requirements in cell and gene therapy	TBD ,
11:15 a.m. - 12:00 p.m.	Supply Chain of Single Use Consumables	Jen Ahearn , GMPact (confirmed)
12:00-12:15 p.m.	Q&A Panel	
12:15 p.m.	Conference Adjournment	

POST-CONFERENCE CONCURRENT WORKSHOPS		
12:15-1:00	Luncheon for Post-Conference Workshop Participants	Magnolia Ballroom
CONCURRENT WORKSHOP #1 LOCATION (TBD)		
1:00-2:30 p.m.	Update on Animal Health Regulations GMP Similarities and Difference between FDA, USDA and EPA	Steven Jones, Boehringer-Ingelheim Lauren Zaleski, USDA TBD, EPA
2:30-2:45 p.m.	Networking Break	Kellogg Concourse
2:45-4:00 p.m.	Update on Animal Health Regulations Challenges and Approaches for CMC Submissions to CVM <ul style="list-style-type: none"> • Navigating the esubmitter template • Hands-on activity using the esubmitter – INAD CMC technical section submission 	Jonathan Houpt, Boehringer-Ingelheim Grace Gowda, UGA
4:00 p.m.	Post-Conference Adjournment	
CONCURRENT WORKSHOP #2 LOCATION (TBD)		
1:00-2:30 p.m.	Control Strategies, Qualification, Validation and Knowledge Management to Reduce Processing Risk	Jen Ahearn, GMPact
2:30-2:45 p.m.	Networking Break	Kellogg Concourse
2:45-4:00 p.m.	Control Strategies, Qualification, Validation and Knowledge Management to Reduce Processing Risk	Jen Ahearn, GMPact
4:00 p.m.	Post-Conference Adjournment	