

# 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
<b>MORNING SESSION - Mahler Hall</b>		
8:00-8:45 a.m.	Welcoming Remarks	<b>TBD</b>
8:45-9:30 a.m.	The Value of Quality	<b>Hans-Joachim Ploss</b> , Boehringer Ingelheim (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.	Update on the Office of Inspections and Investigations	<b>Ivy Sweeney</b> , FDA (invited)
11:00-11:45 a.m.	The FDA is Coming: Are you Ready? A Proactive Approach to 503b Audit Preparedness	<b>Jessica McAlister</b> , Olympia Pharmaceuticals (confirmed)
11:45 a.m. - 12:00 p.m.	Q&A Panel	
12:00-1:00 p.m.	Networking Lunch	Magnolia Ballroom
<b>AFTERNOON SESSION - Mahler Auditorium</b>		
1:00-1:45 p.m.	The Use of AI in FDA GXP Compliance and Drug Approval	<b>Howard Sklamberg</b> , 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	<b>Alan Minsk</b> , 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	<b>Thomas O'Conner</b> , FDA (invited)
4:00-4:45 p.m.	Aseptic manufacturing without automation: readiness, risks and reality	<b>Jessica Chiaruttini</b> , 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
<b>MORNING SESSION - Mahler Auditorium</b>		
8:15-9:00 a.m.	Case Studies from GMP Inspections	<b>Simone Pitts</b> , FDA (invited)
9:00-9:45 a.m.	Health Canada Inspection Trends and Case Studies	<b>TBD</b> , 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	<b>Peter Baker</b> , Live Oak (confirmed)
11:15 a.m. - 12:00 p.m.	When Risk is Ignored: GMP Inspection Pitfalls and Compliance Impace	<b>Ileana Barreto-Pettit</b> , Capitana Audit Solutions (confirmed)
12:00-12:15 p.m.	Q&A Panel	
12:15-1:15 p.m.	Networking Lunch	Magnolia Ballroom
<b>AFTERNOON SESSION - Mahler Auditorium</b>		
1:15-2:00 p.m.	Update from the Office of Pharmaceutical Quality	<b>Ashley Boam</b> , 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	<b>Margareth Marques</b> , USP (confirmed)
4:15-5:00 p.m.	Quality Matters: The Importance of Particulate Matter in Pharmaceutical Quality	<b>Desmond Hunt</b> , USP (confirmed)
5:00-5:15 p.m.	Q&A Panel	
5:30-6:15 p.m.	<b>Shuttle Service to Sanford Stadium</b> <ul style="list-style-type: none"> <li>- Destination: <b>West End Zone Lounge, Sanford Stadium</b></li> <li>- <b>Pick-up:</b> Outside the <b>Georgia Center Hotel Lobby Entrance</b></li> </ul>	
6:00-7:30 p.m.	<b>Celebration Reception</b> <ul style="list-style-type: none"> <li>- <b>Location:</b> West End Zone Lounge, Sanford Stadium</li> <li>- Joined by UGA graduate students and postdocs</li> </ul>	
7:30-8:00 p.m.	<b>Return Shuttle Service to the Georgia Center</b> <ul style="list-style-type: none"> <li>- <b>Pick-up:</b> Sanford Stadium West End Zone Entrance - Bridge Level</li> </ul> <p><b>*NOTE:</b> Shuttle service will be available continuously from 5:30-8:00 p.m.</p>	
<b>Enjoy dinner in Athens!</b> See <a href="https://www.visitathensga.com/">https://www.visitathensga.com/</a> 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
<b>MORNING SESSION - Mahler Auditorium</b>		
8:15-9:00 a.m.	Thoughts on the FDA: Past, Present and Future	<b>Robert Califf</b> , Duke University (invited)
9:00-9:45 a.m.	An Update on CDER's Quality Management Maturity Program	<b>Nyrma CruzRuiz</b> , 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.	Autologous versus allogeneic requirements in cell and gene therapy	<b>TBD</b> ,
11:15 a.m. - 12:00 p.m.	Supply Chain of Single Use Consumables	<b>Jen Ahearn</b> , GMPact (confirmed)
12:00-12:15 p.m.	Q&A Panel	
12:15 p.m.	<b>Conference Adjournment</b>	

<b>POST-CONFERENCE CONCURRENT WORKSHOPS</b>		
12:15-1:00	Luncheon for Post-Conference Workshop Participants	Magnolia Ballroom
<b>CONCURRENT WORKSHOP #1 LOCATION (TBD)</b>		
1:00-2:30 p.m.	Update on Animal Health Regulations  GMP Similarities and Difference between FDA, USDA and EPA	<b>Steven Jones,</b> Boehringer-Ingelheim <b>Lauren Zaleski,</b> Boehringer-Ingelheim <b>TBD,</b> 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"> <li>• Navigating the esubmitter template</li> <li>• Hands-on activity using the esubmitter – INAD CMC technical section submission</li> </ul>	<b>Jonathan Houpt,</b> Boehringer-Ingelheim <b>Grace Gowda,</b> UGA
4:00 p.m.	<b>Post-Conference Adjournment</b>	
<b>CONCURRENT WORKSHOP #2 LOCATION (TBD)</b>		
1:00-2:30 p.m.	Control Strategies, Qualification, Validation and Knowledge Management to Reduce Processing Risk	<b>Jen Ahearn,</b> 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	<b>Jen Ahearn,</b> GMPact
4:00 p.m.	<b>Post-Conference Adjournment</b>	