

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 – Masters Hall | | |
| 8:00-8:30 a.m. | Welcome and Orientation | Dean Kelly Smith and Michael Bartlett, UGA College of Pharmacy |
| 8:30-9:15 a.m. | The Value of Quality | Hans-Joachim Ploss, Boehringer Ingelheim (confirmed) |
| 9:15-9:30 a.m. | Q&A Panel | |
| 9:30-10:00 a.m. | Networking Break | Hill Atrium |
| 10:00-10:45 a.m. | The FDA Drug Inspectorate Updates | Ivy Sweeney, FDA (confirmed) |
| 10:45-11:30 a.m. | Robust, FDA Ready Deviation Writing | Jessica McAlister, Olympia Pharmaceuticals (confirmed) |
| 11:30-11:45 p.m. | Q&A Panel | |
| 11:45 a.m. - 1:00 p.m. | Networking Lunch | Magnolia Ballroom |
| AFTERNOON SESSION – Masters Hall | | |
| 1:00-1:45 p.m. | The Use of AI in FDA GXP Compliance and Drug Approval | Howard Sklamberg, Arnold & Porter (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 | |

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| 2:45-3:15 | Networking Break | Hill Atrium |
| 3:15-4:00 p.m. | The Augmented Auditor: AI as a Catalyst for Better Compliance | Sarah Barkow , Astra Zeneca (confirmed) |
| 4:00-4:45 p.m. | No Barriers to Success: Modern Technology in Sterile Filling Operations | Erika Pfeiler , Valsource (confirmed) |
| 4:45-5:00 p.m. | Q&A Panel | |
| 6:00-8:00 p.m. | Dinner with keynote speaker Multiple Perspectives on Extreme and Compound Weather Events | Magnolia Ballroom Marshall Shepherd , UGA Franklin College of Arts and Sciences |

Wednesday, March 4, 2026

| Time | Event/Topic | Location/Speaker |
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| 7:00-8:15 a.m. | Breakfast Buffet | Magnolia Ballroom |
| MORNING SESSION – Masters Hall | | |
| 8:15-9:00 a.m. | Case Studies from GMP Inspections | Simone Pitts , FDA (confirmed) |
| 9:00-9:45 a.m. | New FDA QMSR Changes for Combination Products and Medical Devices | Marie Mathews , Franklin Mathews Group (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. | 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 Impact | 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 – Masters Hall | | |
| 1:15-2:00 p.m. | Update from the Office of Pharmaceutical Quality | Mehesh Ramanadham , FDA (confirmed) |
| 2:00-2:15 p.m. | Q&A Panel | |

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| 2:15-3:00 p.m. | Hot Topics in GxP regulatory intelligence - Ask the Experts – Open Mic Session | Sarah Barkow , Astra Zeneca (confirmed) TBD – Other Experts |
| 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 - Destination: West End Zone Lounge, Sanford Stadium - Pick-up: Outside the Georgia Center Hotel Lobby Entrance | |
| 6:00-7:30 p.m. | Celebration Reception - Location: West End Zone Lounge, Sanford Stadium | |
| 7:30-8:00 p.m. | Return Shuttle Service to the Georgia Center - Pick-up: Sanford Stadium West End Zone Entrance – Bridge Level *NOTE: Return shuttle service will be available from 7:00-8:15 p.m. | |
| 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 |
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| 7:00-8:15 a.m. | Breakfast Buffet | Magnolia Ballroom |
| MORNING SESSION – Masters Hall | | |
| 8:15-9:00 a.m. | Supply Chain of Single Use Consumables | Jen Ahearn , GMPact (confirmed) |
| 9:00-9:45 a.m. | An Update on CDER's Quality Management Maturity Program | Nyrma CruzRuiz , 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 vs Allogeneic Requirements in Cell & Gene Therapy | Rob Piperno, Sr. , Lachman Consultants (confirmed) |
| 11:15-11:30 a.m. | Q&A Panel | |
| 11:30 a.m. - 12:15 p.m. | Fireside Chat with the former FDA Commissioner | Robert Califf , Duke University (confirmed) |
| 12:15 p.m. | Conference Adjournment | |

| POST-CONFERENCE CONCURRENT WORKSHOPS | | |
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| 12:15-1:00 | Networking Lunch | Magnolia Ballroom |
| CONCURRENT WORKSHOP #1 LOCATION – Room Q – Second Floor | | |
| 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, Boehringer-Ingelheim Nader Elkassabany, former US 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 College of Pharmacy |
| 4:00 p.m. | Post-Conference Adjournment | |
| CONCURRENT WORKSHOP #2 LOCATION – Masters Hall | | |
| 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 | Hill Atrium |
| 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 | |