AGENDA

	Pharmacy Track - Green	*Medical Device Track - Orange*	

Monday, March 8, 2027

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 9, 2027

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		
8:30-8:45 a.m.	Welcome Remarks	**Dean Kelly Smith and Michael Bartlett**, UGA
8:45-9:30 a.m.	Update on Office of Inspections and Investigations	*Ivy Sweeney, FDA (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.	Operational Excellence	**Thomas Friedli, Univ. Of St Gallen**
11:00-11:45 a.m.	AI-Enabled Quality Organization	**Steffan Wanning, Boehringer-Ingelheim**
11:45 a.m.–12:00 p.m.	Q&A Panel	

12:00- 1:00 p.m.	Networking Lunch			Magnolia Ballroom
AFTERNOON SESSION – Masters Hall or Dogwood Hall				
Time	**Pharm Track- Masters Hall**	**Speaker**	**Device Track-Dogwood Hall**	**Speaker**
1:00-1:45 p.m.	European Inspection Trends and Case Studies	TBD, Belgian FAGG (invited)	QSMR Update (including inspection Model) (Last until 1:50 p.m.)	Keisha Thomas & Karen Mosley Joesph
1:45-2:30 p.m.	Inspections from a regulatory perspective	Alan Minsk, AGG (confirmed)	General Wellness Devices/ Devices versus home health aids and companion apps – Regulatory Paradigm	(TBD) (Allison K. invited)
2:30-2:45 p.m.	Q&A Panel		Q&A Panel	
2:45-3:15 p.m.	Networking Break			Hill Atrium
3:15-4:00 p.m.	Annex 1 Update & Implementation Guidelines	Mark Birse, Parexel (confirmed)	Data Integrity from Development to Commercialization	FDA or industry – Invited (Joseph S.)
4:00-4:45 p.m.	Updated changes at CBER	Melissa Mendoza, Hogan, Lovells, Cadwalader	483's and Inspection Trends	Trang Cox
4:45-5:00 p.m.	Q&A Panel* (Masters Hall or Dogwood Hall)			
6:00-8:00 p.m.	Dinner (Need Speaker)			Magnolia Ballroom

Wednesday, March 10, 2027

7:00-8:15 a.m.	Breakfast Buffet		Magnolia Ballroom	
MORNING SESSION – Masters or Dogwood Hall				
Time	**Pharm Track- Masters Hall**	**Speaker**	**Device Track- Dogwood Hall**	**Speaker**
8:15-9:00 a.m.	Case Studies from GMP Inspections	Simone Pitts, FDA Invited*	Generative AI Medical Devices: What FDA Wants and What's Coming Next?	Phillip Desjardins
9:00-9:45 a.m.	AI in Inspections	Sarah Barkow,	AI meets	W. Alex Smith

		AstraZeneca (confirmed)	Cybersecurity – Medical Device	
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.	ICH Q9: do's & don't with risk-based decision-makng	Peter Baker, Live Oak (confirmed)	MDSAP	Johnathan Bis
11:15 a.m. - 12:00 p.m.	Building an FDA-Ready Visual Inpection Program	Ileana Barreto-Pettit, Capitana Aduit Solutions (confirmed)	IMDRF or Regulatory Reliance- Int'l Markets Registration	Evangeline Zelenski
12:00-12:15 p.m.	Q&A			
12:15-1:15 p.m.	Networking Lunch		Magnolia Ballroom	

AFTERNOON SESSION – Masters or Dogwood Hall

Time	Pharm Sessions- Masters Hall	Speaker	Medical Device Track- Dogwood Hall	Speaker
1:15-2:00 p.m.	Update from Office of Pharmaceutical Quality	Ashley Boam, FDA (confirmed)	EU – Regulations Update	Seppe de Galas
2:00-2:45 p.m.	Validating AI Processes	Michelle Vuolo, Tulip Interfaces (confirmed)	China – Regulations Update	Qian Qian Zhu
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.	USP Extractables & Leachable Solutions	Ravikiran Kaja, USP (confirmed)	Integrating Risk Management through Product Lifestyle	Kim Trautman
4:15-5:00p.m.	Revision Preview of Analytical ISQ	Edmond Biba, USP	Combination product – Integrating Change Management	Sujith Kallur Mallikarjuna, BD
5:00-5:15 p.m.	Q&A Panel			
5:15-6:45 p.m.	**Networking Reception**	**Sanford Stadium, West End Zone**	**Reception**	**Hill Atrium**

Thursday, March 11, 2027

7:00-8:15 a.m.	Breakfast Buffet	Magnolia Ballroom
MORNING SESSION – Masters Hall		
8:15-9:00 a.m.	Update on the FDA's Quality Management Maturity (QMM) initiative: update and next steps	**Eric Twum**
9:00-9:45 a.m.	QMM, Data Integrity and Management Review Metrics	**Jen Ahearn, GMPact**
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.	EU Annex Updates	**Mark Birse, Parexel**
11:15-12:00 p.m.	Update on Outsource & Compounding Pharmacy	Hidee Molina, FDA
12:00-12:15p.m.	Q&A Panel	
12:15 p.m.	Conference Adjournment	
POST CONFERENCE CONCURRENT WORKSHOPS		
12:15-1:00	Networking Lunch	Magnolia Ballroom
CONCURRENT WORKSHOP #1 LOCATION (Tentative)		
1:00- 2:30 p.m.	Quality Culture	Jen Ahearn, GMPact Inc. (Masters Hall)
2:30-2:45 p.m.	Networking Break	Kellogg Concourse
2:45-4:00 p.m.	Quality Culture	Jen Ahearn, GMPact Inc. (Masters Hall)
CONCURRENT WORKSHOP #2 LOCATION – Room Q – Second Floor		
1:00-2:30 p.m.	QMSR Implementation	Kim Trautman (Confirmed) Evangeline Zelenski
2:30-2:45 p.m.	Networking Break	Kellogg Concourse

2:45-4:00 p.m.	QMSR Implementation	Kim Trautman (Confirmed) Evangeline Zelenski
4:00 p.m.	**Post-Conference Adjournment**	
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**	