

AGENDA

Monday, March 6, 2023

Time	Event/Topic	Location/Speaker
1:30-5:00 p.m.	Registration	Conference Registration Desk
PRE-CONFERENCE TUTORIAL – College of Pharmacy Pharmacy South Building – Room 101		
2:00-3:15 p.m.	Quality and Compliance Management for Remote (Virtual) Operations	David Chesney , Chesney Consulting
3:15-3:30 p.m.	Break	
3:30-4:30 p.m.	Quality and Compliance Management for Remote (virtual) Operations (continued)	David Chesney , Chesney Consulting
5:00-7:00 p.m.	Welcome Reception and Tours	Wilson Pharmacy Bldg. - 2nd Floor Corridor

Tuesday, March 7, 2023

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 and Orientation	Dean Kelly M. Smith & Michael Bartlett , University of Georgia
8:45-9:30 a.m.	Update from the Office of Regulatory Affairs	Alonza Cruse , FDA ORA
9:30-9:45 a.m.	Q&A Panel	
9:45-10:15 a.m.	Networking Break	Pecan Tree Galleria
10:15-11:00 a.m.	GMP challenges in 503b compounding pharmacy	Charles Richardson , KRS Biotech
11:00-11:45 a.m.	Cybersecurity Challenges for Pharmaceutical Industry	Samuel Eubanks , Lonza
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

1:00-1:45 p.m.	Update from the Office of Pharmaceutical Quality	Ashley Boam , FDA CDER
1:45-2:30 p.m.	Send Money, Guns and Lawyers (Well, Not Guns): Legal perspectives on data integrity	Alan Minsk , Arnall Golden Gregory LLP
2:30-2:45 p.m.	Q&A Panel	
2:45-3:15	Networking Break	Hill Atrium
3:15-4:00 p.m.	Deviation investigations: Human error is not the root cause	James Vesper , Valsource
4:00-4:45 p.m.	Navigating DSCSA Implementation	Madeleine Giaquinto , Greenleaf Health, Inc.
4:45-5:00 p.m.	Q&A Panel	
6:30-8:30 p.m.	Dinner Recent emergency preparedness issues related to pharmaceutical needs	Magnolia Ballroom Cham Dallas , University of Georgia

Wednesday, March 8, 2023

Time	Event/Topic	Location/Speaker
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	Ileana Barreto-Pettit , FDA ORA
9:00-9:45 a.m.	Health Canada Inspection Trends and Case Studies	Sandi Dube , 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.	Use of new technologies in data integrity and quality decision making	Patrick Day , Lachman Consulting Services
11:15 a.m. - 12:00 p.m.	Science of Quality	Jennifer Ahearn , Engineering Systems
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.	The Lost Art of Internal Auditing	Mike Levitt , Quality Executive Partners
2:00-2:45 p.m.	Update on OOS guidance	Rick Friedman , FDA, CDER
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.	FDA’s Regulatory Oversight of Regenerative Medicine Products	Melissa Mendoza , FDA CDER
4:15-5:00 p.m.	USP Approach to standards for biologics	Fouad Atouf , USP
5:00-5:15 p.m.	Q&A Panel	
5:15-6:45 p.m.	Networking Reception, joined by UGA graduate students and postdocs	Hill Atrium
<p>Enjoy dinner in Athens! See visitathensga.com for inspiration for your night on the town.</p>		

Thursday, March 9, 2023

Time	Event/Topic	Location/Speaker
7:00-8:15 a.m.	Breakfast Buffet	Magnolia Ballroom
MORNING SESSION – Masters Hall		
8:15-9:00 a.m.	Update on QMM	Jennifer Maguire , FDA CDER
9:00-9:45 a.m.	Quality Metrics & Maturity – Keys to Q Excellence	Steve Greer , Engineering Systems
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.	Keeping pace with innovation and maintaining regulatory oversight	Mark Birse , Paraxel
11:15 a.m. - 12:00 p.m.	Evolution of regulatory surveillance strategies	Sarah Barkow , BMS
12:00-12:15 p.m.	Q&A Panel	
12:15 p.m.	Conference Adjournment	

POST-CONFERENCE TUTORIAL

12:15-1:00

Luncheon for Post-Conference Tutorial Participants

Kellogg Concourse

POST-CONFERENCE TUTORIAL

Room R – Second Floor

1:00-2:30 p.m.

Out of Specification Investigations

Jennifer Ahearn,
Engineering Systems

2:30-2:45 p.m.

Networking Break

Kellogg Concourse

2:45-4:00 p.m.

Implementation of new OOS Guidance

Marie Mathews,
Mathews Consulting

4:00 p.m.

Post-Conference Adjournment

Continuing Education (CE) credit available through this tutorial only.