

# AGENDA

Monday, March 6, 2023

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

Tuesday, March 7, 2023

Time	Event/Topic	Location/Speaker
7:00-8:30 a.m.	Breakfast Buffet	Dogwood Hall
7:30-8:30 a.m.	Late Registration	Conference Registration Desk
<b>MORNING SESSION - Masters Hall</b>		
8:30-8:45 a.m.	Welcome and Orientation	<b>Dean Kelly M. Smith &amp; Michael Bartlett</b> , University of Georgia
8:45-9:30 a.m.	Update from the Office of Regulatory Affairs	<b>Alonza Cruse</b> , 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	<b>Charles Richardson</b> , KRS Global Biotechnology
11:00-11:45 a.m.	Cybersecurity Challenges for Pharmaceutical Industry	<b>Samuel Eubanks</b> , Lonza
11:45 a.m. - 12:00 p.m.	Q&A Panel	
12:00-1:00 p.m.	Networking Lunch	Magnolia Ballroom

<b>AFTERNOON SESSION – Masters Hall</b>		
1:00-1:45 p.m.	Update from the Office of Pharmaceutical Quality	<b>Ashley Boam</b> , FDA CDER
1:45-2:30 p.m.	Send Money, Guns and Lawyers (Well, Not Guns): Legal perspectives on data integrity	<b>Alan Minsk</b> , 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	<b>James Vesper</b> , Valsource
4:00-4:45 p.m.	Navigating DSCSA Implementation	<b>Madeleine Giaquinto</b> , 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 <b>Cham Dallas</b> , University of Georgia

### Wednesday, March 8, 2023

<b>Time</b>	<b>Event/Topic</b>	<b>Location/Speaker</b>
7:00-8:15 a.m.	Breakfast Buffet	Magnolia Ballroom
<b>MORNING SESSION – Masters Hall</b>		
8:15-9:00 a.m.	Case Studies from GMP Inspections	<b>Ileana Barreto-Pettit</b> , FDA ORA
9:00-9:45 a.m.	Health Canada Inspection Trends and Case Studies	<b>Sandi Dube</b> , 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	<b>Patrick Day</b> , Lachman Consulting Services
11:15 a.m. - 12:00 p.m.	Science of quality	<b>Jennifer Ahearn</b> , Engineering Systems
12:00-12:15 p.m.	Q&A Panel	
12:15-1:15 p.m.	Networking Lunch	Magnolia Ballroom

<b>AFTERNOON SESSION – Masters Hall</b>		
1:15-2:00 p.m.	The Lost Art of Internal Auditing	<b>Mike Levitt</b> , Quality Executive Partners
2:00-2:45 p.m.	Update on OOS guidance	<b>Rick Friedman</b> , 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.	Policy updates on biologics and cell therapies	<b>Melissa Mendoza</b> , FDA CDER
4:15-5:00 p.m.	USP Approach to standards for biologics	<b>Fouad Atouf</b> , 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><b>Enjoy dinner in Athens!</b>            See <a href="http://bit.ly/gmpdinner">http://bit.ly/gmpdinner</a> for inspiration for your night on the town.</p>		

**Thursday, March 9, 2023**

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

<b>POST-CONFERENCE TUTORIAL</b>		
12:15-1:00	Luncheon for Post-Conference Tutorial Participants	Kellogg Concourse
<b>POST-CONFERENCE TUTORIAL Room R – Second Floor (Tentative)</b>		
1:00-2:30 p.m.	Out of Specification Investigations	<b>Jennifer Ahearn,</b> Engineering Systems
2:30-2:45 p.m.	Networking Break	Kellogg Concourse
2:45-4:00 p.m.	Implementation of new OOS Guidance	<b>Marie Mathews,</b> Mathews Consulting
4:00 p.m.	<b>Post-Conference Adjournment</b>	
<i>Continuing Education (CE) credit available through this tutorial only.</i>		