

AGENDA

Monday, March 4, 2024

| Time | Event/Topic | Location/Speaker |
|----------------|-------------------|------------------------------|
| 4:00-6:00 p.m. | Registration | Conference Registration Desk |
| 5:00-7:00 p.m. | Welcome Reception | Hill Atrium |

Tuesday, March 5, 2024

| 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 | Hill Atrium |
| 10:15-11:00 a.m. | IMPALA industry consortium: Collaboration and Analytics use cases in R&D quality | Robert Studdt, Janssen |
| 11:00-11:45 a.m. | Building Quality Management Science to Improve Drug Manufacturing | Thomas Friedli, University of Saint Gallen's |
| 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. | Process capability-based control strategies – A logical next step for ensuring product quality | Eric Jayjock, Vertex |
| 1:45-2:30 p.m. | USP's Evolving position on the use of Endotoxin Testing and Rapid Microbiological Methods | Huiping Tu and Leslie Furr, USP |
| 2:30-2:45 p.m. | Q&A Panel | |
| 2:45-3:15 | Networking Break | Hill Atrium |

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| 3:15-4:00 p.m. | Impact of AI in Regulatory, Quality and Manufacturing | Benjamin Stevens , GSK |
| 4:00-4:45 p.m. | Areas of Consideration for AI in Drug Manufacturing | Thomas O’Conner , FDA |
| 4:45-5:00 p.m. | Q&A Panel | |
| 6:30-8:30 p.m. | Dinner “Drug Shortages” | Magnolia Ballroom Tim Southern , South Dakota Department of Public Health |

Wednesday, March 6, 2023

| 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 ORA |
| 9:00-9:45 a.m. | Health Canada Regulatory Updates | Teresa Forlini , 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. | Data Integrity Risk Assessments: Mapping, Mitigation, and Continuous Improvement | Kir Henrici , Henrici Group |
| 11:15 a.m. - 12:00 p.m. | Cybersecurity and Automation in Pharmaceutical Manufacturing | Kurt In Albon , Lonza |
| 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. | ICH Q12 and Q14: Inspection-Related Considerations | Ashley Boam , FDA |
| 2:00-2:45 p.m. | Insights on FDA 483 Observations | Ileana Barreto-Pettit , Parexel |
| 2:45-3:00 p.m. | Q&A Panel | |

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| 3:00-3:30 p.m. | Networking Break | Hill Atrium |
| 3:30-4:15 p.m. | Responsibilities as a Sponsor of GxP Outsourced Activities | Jen Ahearn , GMPACT |
| 4:15-5:00 p.m. | CGT Commercialization challenges and strategies when using CDMOs | Christine Feaster , Quality Executive Partners |
| 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 |
| Enjoy dinner in Athens! See http://bit.ly/gmpdinner2024 for inspiration for your night on the town. | | |

Thursday, March 7, 2024

| 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. | Predicting GMP Quality Risks at Manufacturing Sites | Jerry Chapman , REDICA Systems |
| 9:00-9:45 a.m. | Update on CDER’s Quality Management Maturity Program | Jennifer Maguire , FDA |
| 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. | Health System Insights for Regulators on Pharmaceutical Quality | Philip Almeter & Rob Lodder , University of Kentucky |
| 11:15 a.m. - 12:00 p.m. | Legal Perspective – Artificial Intelligence in Regulatory Operations | Alan Minsk , AGG |
| 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 Q – Second Floor | | |

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| 1:00-2:30 p.m. | Effective Remediation Strategies | Jen Ahearn , GMPact |
| 2:30-2:45 p.m. | Networking Break | Kellogg Concourse |
| 2:45-4:00 p.m. | Effective Remediation Strategies | Jen Ahearn , GMPact |
| 4:00 p.m. | Post-Conference Adjournment | |