



UNIVERSITY OF
GEORGIA
College of Pharmacy



50th International Good Manufacturing Practices Conference

March 2-5, 2026

FROM THE CHAIR

Dear Colleagues,

I am pleased to welcome you to the 50th International Good Manufacturing Practices Conference. It is my privilege to serve as chair of the planning committee for this year's event, which is being held in a hybrid environment. I invite you to join, engage, and learn!



This conference was established in conjunction with the U.S. Food and Drug Administration in 1976 to create an annual ongoing dialogue between regulatory agencies and the pharmaceutical industry on important issues in drug compliance and quality. The conference is widely recognized as the top international GMP meeting in the world and offers attendees the unique opportunity to meet with regulators and industry experts.

The conference agenda is filled with experts from a wide variety of areas critical to drug discovery and development. This year, the conference will focus on many challenges in manufacturing and quality systems. The conference will include sessions on compounding pharmacy, uses of AI, sterile filling operations, data governance, risk management, ophthalmic products, particulate matter, cell and gene therapies, along with many updates from various FDA offices and GMP inspection trends.

I thank you for your continued support of this conference!

A handwritten signature in black ink, which appears to read "Michael G. Bartlett". The signature is fluid and cursive.

Michael G. Bartlett, Ph.D., Chair
University Professor
Associate Dean for Science Education, Research and Technology
College of Pharmacy
University of Georgia

CONTENTS

Get Connected	4
Sponsor and Exhibitor Booth Info	5
Agenda.....	6-8
Sponsors	9-11
Program Committee	14
Speaker Information	15-25
Georgia Center Map.....	26-27
Save the Date.....	28



GET CONNECTED

CONNECTING TO WI-FI

Join the Wi-Fi network named **UGA Visitors**.

Enter your mobile phone number and agree to the terms & conditions.

Once you receive a login code on your SMS-enabled device, enter your code on the Wi-Fi network landing page.

Open your internet browser and navigate to any website.

CONFERENCE FEEDBACK SURVEY

Your input is very important to our planning process.

Please help improve our conference by completing a quick survey online on Thursday following conference adjournment!

Visit bit.ly/gmp-50 or scan the QR Code



POST CONFERENCE MATERIALS

Post Conference access to the presentation slides and recordings from the 2026 program:

1. Go to internationalgmp.com
2. Under “Agenda” menu, select
 - “2026 Conference Presentations”
 - “2026 Conference Recordings”
3. Use password: **#50gmp2026**



SPONSOR AND EXHIBITOR BOOTH INFO

**Sponsor and Exhibitor Booths will be open
until Thursday, March 5 at 10:30 am.**

ALORA
pharmaceuticals



AGENDA

Monday, March 2, 2026

Time	Event/Topic	Location/Speaker
3:30 - 5:00pm	Registration	Conference Registration Desk
5:00 - 7:00pm	Welcome Reception	Hill Atrium

Tuesday, March 3, 2026

Time	Event/Topic	Location/Speaker
7:00 - 8:30am	Breakfast Buffet	Magnolia Ballroom
7:30 - 8:30am	Late Registration	Conference Registration Desk
MORNING SESSION – Masters Hall		
8:00 - 8:30am	Welcome and Orientation	Dean Kelly Smith and Michael Bartlett <i>UGA College of Pharmacy</i>
8:30 - 9:15am	The Value of Quality	Hans-Joachim Ploss <i>Boehringer-Ingelheim</i>
9:15 - 9:30am	Q&A Panel	
9:30 - 10:00am	Networking Break	Hill Atrium
10:00 - 10:45am	The FDA Drug Inspectorate Updates	Ivy Sweeney <i>FDA</i>
10:45 - 11:30am	The FDA is Coming: Are you Ready? A Proactive Approach to 503b Audit Preparedness	Jessica McAlister <i>Olympia Pharmaceuticals</i>
11:30 - 11:45am	Q&A Panel	
11:45am - 1:00pm	Networking Lunch	Magnolia Ballroom
AFTERNOON SESSION – Masters Hall		
1:00 - 1:45pm	The Use of AI in FDA GXP Compliance and Drug Approval	Howard Sklamberg <i>Arnold & Porter</i>
1:45 - 2:30pm	FDA and non-FDA issues to consider with non-compliance beyond 483s and warning letters	Alan Minsk <i>AGG</i>
2:30 - 2:45pm	Q&A Panel	
2:45 - 3:15pm	Networking Break	Hill Atrium
3:15 - 4:00pm	The Augmented Auditor: AI as a Catalyst for Better Compliance	Sarah Barkow <i>Astra Zeneca</i>
4:00 - 4:45pm	No Barriers to Success: Modern Technology in Sterile Filling Operations	Erika Pfeiler <i>Valsource</i>
4:45 - 5:00pm	Q&A Panel	
6:00 - 8:00pm	Dinner with keynote speaker Talk title: Multiple Perspectives on Extreme and Compound Weather Events	Magnolia Ballroom Marshall Shepherd <i>UGA Franklin College of Arts and Sciences</i>

Wednesday, March 4, 2026

Time	Event/Topic	Location/Speaker
7:00 - 8:15am	Breakfast Buffet	Magnolia Ballroom
MORNING SESSION – Masters Hall		
8:15 - 9:00am	Case Studies from GMP Inspections	Simone Pitts <i>FDA</i>
9:00 - 9:45am	From Fragmented Data to Predictive Quality: Integrating Internal and External Signals to Predict Supply Chain Risk	Marie Mathews <i>Franklin Mathews Group</i>
9:45 - 10:00am	Q&A Panel	
10:00 - 10:30am	Networking Break	Hill Atrium
10:30 - 11:15am	Data governance & Lean theory: Achieving data integrity through process excellence	Peter Baker <i>Live Oak</i>
11:15am - 12:00pm	When Risk is Ignored: GMP Inspection Pitfalls and Compliance Impact	Ileana Barreto-Pettit <i>Capitana Audit Solutions</i>
12:00 - 12:15pm	Q&A Panel	
12:15 - 1:15pm	Networking Lunch	Magnolia Ballroom
AFTERNOON SESSION – Masters Hall		
1:15 - 2:00pm	Update from the Office of Pharmaceutical Quality	Mehesh Ramanadham <i>FDA</i>
2:00 - 2:15pm	Q&A Panel	
2:15 - 3:00pm	Hot Topics in GxP regulatory intelligence Ask the Experts – Open Mic Session	Sarah Barkow <i>AstraZeneca</i> TBD – Other Experts
3:00 - 3:30pm	Networking Break	Hill Atrium
3:30 - 4:15pm	Quality requirements for Ophthalmic Products	Margareth Marques <i>USP</i>
4:15 - 5:00pm	Quality Matters: The Importance of Particulate Matter in Pharmaceutical Quality	Desmond Hunt <i>USP</i>
5:00 - 5:15pm	Q&A Panel	
5:30 - 6:15pm	Shuttle Service to Sanford Stadium - Destination: West End Zone Lounge, Sanford Stadium - Pick-up: Outside the Georgia Center Hotel Lobby Entrance *NOTE: For attendees driving themselves, see page 13 Self Parking and Directions for details	
6:00 - 7:30pm	Celebration Reception - Location: West End Zone Lounge, Sanford Stadium	
7:30 - 8:00pm	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.		

AGENDA

Thursday, March 5, 2026

Time	Event/Topic	Location/Speaker
7:00 - 8:15am	Breakfast Buffet	Magnolia Ballroom
MORNING SESSION – Masters Hall		
8:15 - 9:00am	Thoughts on the FDA: Past, Present and Future	Robert Califf <i>Duke University</i>
9:00 - 9:45am	An Update on CDER's Quality Management Maturity Program	Nyrma CruzRuiz <i>FDA</i>
9:45 - 10:00am	Q&A Panel	
10:00 - 10:30am	Networking Break	Hill Atrium
10:30 - 11:15am	Autologous vs Allogeneic Requirements in Cell & Gene Therapy	Rob Piperno, Sr. <i>Lachman Consultants</i>
11:15am - 12:00pm	Supply Chain of Single Use Consumables	Jen Ahearn <i>GMPact</i>
12:00 - 12:15pm	Q&A Panel	
12:15pm	Conference Adjournment	
POST-CONFERENCE WORKSHOPS		
12:15 - 1:00pm	Networking Luncheon	Magnolia Ballroom
CONCURRENT WORKSHOP #1 LOCATION – Room Q – Second Floor		
1:00 - 2:30pm	Update on Animal Health Regulations GMP Similarities and Difference between FDA, USDA and EPA	Steven Jones <i>Boehringer-Ingelheim</i> Lauren Zaleski <i>Boehringer-Ingelheim</i> Nader Elkassabany <i>former US EPA</i>
2:30 - 2:45pm	Networking Break	Kellogg Concourse
2:45 - 4:00pm	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 <ul style="list-style-type: none"> – INAD CMC technical section submission 	Jonathan Houpt <i>Boehringer-Ingelheim</i> Grace Gowda <i>UGA College of Pharmacy</i>
4:00pm	Post-Conference Adjournment	
CONCURRENT WORKSHOP #2 LOCATION – Masters Hall		
1:00 - 2:30pm	Control Strategies, Qualification, Validation and Knowledge Management to Reduce Processing Risk	Jen Ahearn <i>GMPact</i>
2:30 - 2:45pm	Networking Break	Hill Atrium
2:45 - 4:00pm	Control Strategies, Qualification, Validation and Knowledge Management to Reduce Processing Risk	Jen Ahearn <i>GMPact</i>
4:00pm	Post-Conference Adjournment	

PLATINUM SPONSOR

ALORA
pharmaceuticals

At Alora Pharmaceuticals, it's our commitment to provide essential medicines. We don't shy away from the real health needs patients face - we take them head on, so patients get the real-world results they deserve.

Endocrinology

DTE Thyroid Products

Neurology

Parkinson's & ADHD Treatments

Women's Health

Prenatals & Low Dose Birth Control

Dermatology

Hematology

Pain Management

Nutritional Supplements



Scan to learn more about
Alora Pharmaceuticals

150+
products

7
therapeutic
areas

The Alora Family of Companies

Acella
PHARMACEUTICALS, LLC

Avion
PHARMACEUTICALS

TRIGEN
LABORATORIES

VERTICAL
PHARMACEUTICALS, LLC

SOVEREIGN
PHARMACEUTICALS

Osmotica
Pharmaceuticals

Alpharetta, GA 30005 | 1-800-541-4802 | 3963-v1.1 © 2025 Alora Pharmaceuticals, LLC. All rights reserved.

GOLD SPONSOR



SILVER SPONSORS

Our team of pharmaceutical regulatory experts provide assistance with quality management system development and strategies, GMP/GLP/GCP assessments, Mock-FDA inspections, regulatory submissions, and more, all to help your organization succeed in this complex and competitive regulatory environment.



Lisa
El-Shall



Jeb
Hunter



Victoria
Pankovich



EAS Consulting Group

A Certified Group Company

easconsultinggroup.com



**Boehringer
Ingelheim**

GMP Celebration Reception Shuttle Information:

5:30 – 6:15 p.m. | Shuttle Service from Georgia Center to Sanford Stadium:

Destination: West End Zone Lounge, Sanford Stadium

Pick-up: Outside of the Georgia Center Hotel Lobby Entrance (Carlton St.)

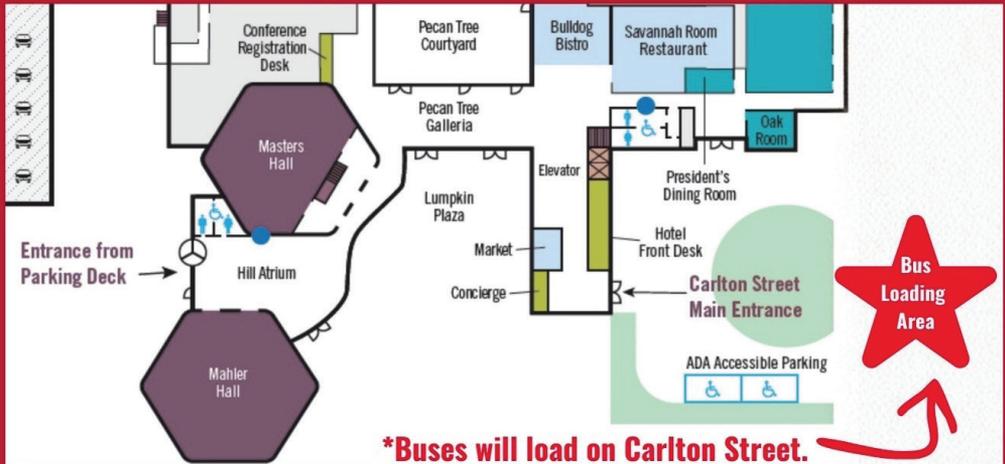
6:00 – 7:30 p.m. | GMP Celebration Reception

Location: West End Zone Lounge, Sanford Stadium

Directions: Take the elevator to Level 2.

7:00 – 8:15 p.m. | Return Shuttle Service to the Georgia Center

Pick-up: Sanford Stadium West End Zone – Bridge Level (Level 3)



Self Parking and Directions

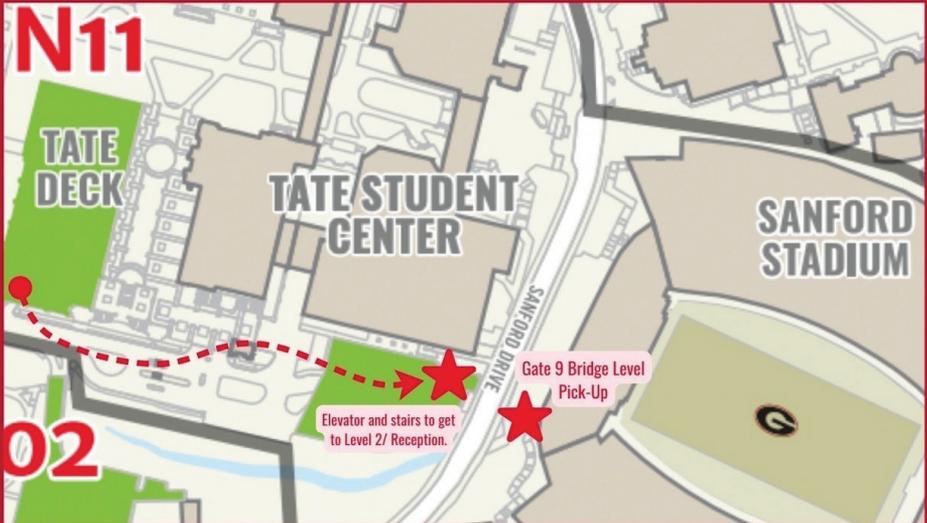
Attendees Choosing to Self-Park:

Parking is available in the Tate Deck (N11) located at
45 Baxter St, Athens, GA 30602.

The deck is free after the hours of 5 p.m..

Tate Deck to West End Zone:

Exit deck on Ground Level. The elevator and stair access for the West End Zone Lounge is located to the right of the Tate Family Gate (or Dawg Walk). Go up to Level 2 to reception (use the map below).





**UNIVERSITY OF
GEORGIA**
College of Pharmacy

COMMIT TO CREATE HEALTHIER COMMUNITIES



rx.uga.edu/academic-programs

2026 PROGRAM COMMITTEE

Michael Bartlett, Ph.D. (Chair)
University of Georgia

Jennifer Ahearn
GMPACT, LLC

Sarah Barkow
AstraZeneca

Ileana Barreto-Pettit
Capitana Audit Solutions

Mark Birse
Parexel International

John Brennan
EAS Consulting Group

Ron Coleman
IHL Consulting

Seppe De Gelas
Hyloris Pharmaceuticals

Monica Escobar
NDA Group AB

Robert Geiger, Ph.D.
Lupin Manufacturing Solutions

Grace Gowda, Ph.D., RAC
University of Georgia

Steve Greer
Genesis Assist

Johnna Hodges
University of Georgia

Alexander Jacks, III
Axogen

Kristen Mandello, D.V.M.
Zoetis, Inc.

Marie Mathews
Franklin Mathews Group

Crystal Mersh
Quality Executive Partners (QxP)

Alan Minsk
Arnall Golden Gregory, LLP

Bill Paulson
IPQ

Prabhakar Reddy, Ph.D.
USP

Gurvinder Singh Rekhi, Ph.D.
University of Georgia

Jean Raymer
Boehringer Ingelheim Pharm.

Sam Silva, Ph.D.
FK Biotecnologia Sa (Brazil)

Evangeline Zielinski
University of Georgia

SPEAKERS



Jennifer Ahearn

CEO/Founder

GMPACT, LLC

Jennifer Ahearn specializes in pharmaceutical and medical device regulatory compliance. She has served numerous roles within the FDA including bench chemist, domestic and international investigator, technical liaison for the FDA's Office of Criminal Investigations, and member of the FDA's National Training Cadre making her an expert in the interpretation and application of cGMP regulations in 21 CFR 210/211 relating to pharmaceutical manufacturing, and 21 CFR 820 relating to medical devices.

Ahearn has assisted pharmaceutical and medical device companies preparing for FDA inspections, as well as responding to FDA 483 observations after an inspection. She has worked to resolve technical and FDA compliance issues for virtually all pharmaceutical dosage forms and medical device classes. Jennifer has worked with manufacturers with such aspects as sterility, material supply chain, vendor auditing, validation programs, laboratory and manufacturing investigations, laboratory and manufacturing audits, and CAPA implementation.

Supply Chain of Single Use Consumables

Thursday 11:15am - 12:00pm

WORKSHOP: Control Strategies, Qualification, Validation and Knowledge Management to Reduce Processing Risk

Thursday 1:00 - 4:00pm



Peter E. Baker

President

*Live Oak Quality
Assurance LLC*

Peter E. Baker is a consultant specializing in Data Governance and Quality Risk Management. He spent 11 years as an FDA Drug Investigator, with 7 of those years spent working in FDA's overseas offices located in India, China and Chile. Peter was named FDA Investigator of the Year in 2013 for his work uncovering serious breaches in data integrity, and has performed more than 100 foreign drug inspections around the world on behalf of the FDA.

Data governance & Lean theory: Achieving data integrity through process excellence

Wednesday 10:30 - 11:15am



Sarah Barkow, Ph.D.

*Senior Director, Proactive
Compliance & Innovation*

AstraZeneca

Sarah Barkow, Ph.D., is the Senior Director of Proactive Compliance & Innovation at AstraZeneca. In this role, she spearheads initiatives to enhance regulatory compliance and drive innovative solutions as part of Global Quality Audit, leveraging the team's experience. Sarah owns the inspection process at AZ and leads both the GMP/GDP regulatory intelligence process and external engagement strategy.

Prior to AstraZeneca, Sarah was the Director of GxP External Engagement at Bristol Myers Squibb, working closely with PhRMA, BIO, IFPMA and other trade organizations and tracking regulatory and policy developments across the GxP realm. Sarah joined BMS from FDA, where she served as a Senior Advisor and Acting Director in the FDA's Office of Compliance. Her contributions include drafting key guidance and policy documents, as well as inspectional compliance programs and warning letters. She also has a background in immunoassay development from Beckman Coulter.

Sarah holds a Ph.D. in Physical Chemistry from MIT where she researched molecular motors.

The Augmented Auditor: AI as a Catalyst for Better Compliance

Tuesday 3:15 - 4:00pm

Hot Topics in GxP regulatory intelligence Ask the Experts – Open Mic Session

Wednesday 2:15 - 3:00pm

SPEAKERS



Ileana Barreto-Pettit, R.N., M.P.H.

President

Capitana Audit Solutions LLC

Ileana Barreto-Pettit is an internationally recognized regulatory compliance expert with over 24 years of experience at the U.S. Food and Drug Administration, most recently serving as Drug National Expert (Subject Matter Expert) within the Office of Regulatory Affairs (ORA) before her retirement in 2023. Throughout her career, Ms. Barreto-Pettit conducted hundreds of inspections worldwide, where she effectively identified significant Good Manufacturing Practices (GMP) deficiencies that resulted in numerous regulatory actions.

When Risk is Ignored: GMP Inspection Pitfalls and Compliance Impact

Wednesday, 11:15am - 12:00pm

With extensive knowledge and understanding of FDA regulations and expectations, Ms. Barreto-Pettit served as a Senior Trainer in the FDA Drug School for 17 years. In this role, she trained hundreds of new drug investigators and compliance officers on 21 CFR 211 drug regulations and the inspectional process of sterile and non-sterile pharmaceutical manufacturers.

Ms. Barreto-Pettit is a respected Speaker who has represented the FDA, international regulatory organizations, and consulting companies in various agency, national, and international pharmaceutical conferences for the past 26 years to share her insights on regulatory compliance. She brings a wealth of knowledge in pharmaceutical regulatory compliance, combining extensive hands-on inspection experience with a deep understanding of GMP regulations and evolving FDA expectations. Her expertise spans across various aspects of drug manufacturing, from pre-approval audits to post-market surveillance, making her an invaluable asset in navigating complex quality and compliance challenges in the pharmaceutical industry.



Robert Califf, MD, MACC

*Instructor in Medicine in
the Division of Cardiology,
former Commissioner
of the FDA*

Robert Califf, MD, MACC, is an Instructor in Medicine in the Division of Cardiology. Dr. Califf was the Commissioner of Food and Drugs in 2016-2017 and in 2022-2025. Prior to his time as Commissioner, he was Deputy Commissioner for Medical Products and Tobacco from February 2015 to February 2016. Between his stints at FDA he was Head of Medical Policy and Strategy at Verily Life Sciences and Google Health.

Thoughts on the FDA: Past, Present and Future

Thursday 8:15 - 9:00am

Prior to joining the FDA, Dr. Califf was a professor of medicine and vice chancellor for clinical and translational research at Duke University. He also served as director of the Duke Translational Medicine Institute and founding director of the Duke Clinical Research Institute. A nationally and internationally recognized expert in cardiovascular medicine, health outcomes research, healthcare quality, and clinical research, Dr. Califf has led many landmark clinical trials and is one of the most frequently cited authors in biomedical science, with more than 1,200 publications in the peer-reviewed literature.



Nyрма Cruz Ruiz

Consumer Safety Officer

FDA

Nyрма Cruz Ruiz is a leader whose career is built on a foundational passion for science. Beginning her journey as a chemist, she has leveraged that deep scientific expertise across an impressive 25-year career dedicated to quality and patient safety in the pharmaceutical and medical device industries.

An Update on CDER's Quality Management Maturity Program

Thursday 9:00 - 9:45am

Her path has provided her with a holistic understanding of the product lifecycle, spanning roles in the QC Laboratory, Technical Operations, Manufacturing, and Supplier Quality. This hands-on experience is complemented by a Lean Green Belt certification and an MBA. For the past two years, she has served as a Consumer Safety Officer in the U.S. FDA's Center for Drug Evaluation and Research, Office of Pharmaceutical Quality, Office of Quality Surveillance, where she applies her comprehensive industry knowledge to proactively monitor and assess the quality of the drug supply.

She is passionate about building high-performing teams and championing a proactive, risk-based approach to quality.

SPEAKERS



Nader Elkassabany, Ph.D

*Regulatory Affairs Director
at former US EPA*

WORKSHOP: Update on Animal Health Regulations

Thursday 1:00 - 4:00pm

Nader Elkassabany is a regulatory affairs professional with more than 28 years of experience across public and private sectors. He has spent the last 13 years in Regulatory Affairs director roles at S.C. Johnson, Merial, Boehringer-Ingelheim Animal Health, and Elanco Animal Health, where he supervised teams dedicated to securing and maintaining federal and state registrations for consumer and animal health pesticide products.

Prior to his entry into private industry, Dr. Elkassabany served in the Office of Pesticides Program in the USEPA for 15 years. During his tenure at EPA OPP, Dr. Elkassabany advanced through several managerial roles, including three years as the Branch Chief of the Risk Assessment and Science Support branch of the Antimicrobial Division. He was awarded several bronze medals for his achievements on a variety of projects.

In his early career, Dr. Elkassabany was a research assistant in the Department of Entomology at the University of Arkansas, Fayetteville, for five years. He also taught as an adjunct professor of microbiology for Montgomery County Community College in Rockville, Md., for 12 years. Dr. Elkassabany continues to enjoy teaching and is currently teaching two courses in the Animal Health Regulatory Affairs Graduate Certificate program at Kansas State University.

Dr. Elkassabany received a Bachelor of Science in Agriculture from the University of Alexandria in Egypt and a Master of Science in Entomology from the University of Tennessee, Knoxville. He earned his Ph.D. in Entomology from the University of Arkansas, Fayetteville.



Grace Gowda

*Program Director,
International Biomedical
Regulatory Sciences Program*

*Associate Professor,
UGA College of Pharmacy*

WORKSHOP: Update on Animal Health Regulations

Thursday 1:00 - 4:00pm

Grace Gowda is the Program Director of the International Biomedical Regulatory Sciences Program and an Associate Professor in the College of Pharmacy. She has a Ph.D. in Pharmacology and Toxicology from the University of Texas at Austin, a Masters in Pharmacy (Pharmacology) from Nagpur University, and Bachelor's in Pharmacy from University of Madras, India. She also has a Regulatory Affairs Certification from RAPS and is a RAPS Fellow.

Grace has more than 25 years of experience in the pharmaceutical industry. Her areas of experience include product development, basic research in the field of neuroscience, clinical research and trials in mental health, targeted drug delivery in immunology, clinical and quality strategy for registration and maintenance of products and regulatory policy.

In her position within the college of Pharmacy, she is responsible for overseeing the Masters of Science programs and multiple graduate certificate programs in International Biomedical Regulatory Sciences. She also is part of the Regulatory Knowledge and Support program within the Georgia Clinical and Translational Science Alliance (GA CTSA) and sits on the board of the Association for Graduate Regulatory Educators.

Grace has held leadership positions in national and international trade associations and has represented the U.S. animal health industry in Veterinary International Conference of Harmonization (VICH) and four animal health user fee negotiations with the FDA. Her commitment and service in leadership roles with Healthcare Business Women Association (HBA) and American Association of Pharmaceutical Scientists (AAPS) were recognized with Service Awards.

SPEAKERS



Jonathan Houpt

Associate Director of Global Regulatory Affairs CMC

Boehringer-Ingelheim

WORKSHOP: Update on Animal Health Regulations

Thursday 1:00 - 4:00pm

Jonathan Houpt is an accomplished regulatory affairs leader with more than two decades of experience spanning pharmaceuticals in both human and animal health. He currently serves as Associate Director of Global Regulatory Affairs CMC at Boehringer Ingelheim Animal Health, where he leads a team responsible for global CMC strategy, regulatory submissions, and lifecycle management across internal manufacturing sites and CMOs.

Jonathan's expertise includes global regulatory filings, Drug Master Files, Veterinary Master Files, Active Substance Master Files, and Certificates of Suitability. He is recognized for his ability to guide cross functional teams, influence regulatory strategy, and collaborate effectively with health authorities worldwide.

Prior to his current role, Jonathan held progressive regulatory positions at Boehringer Ingelheim, Meril, Hospira, and Covidien/Mallinckrodt, as well as earlier roles in quality control and laboratory management. His career reflects a strong foundation in technical problem solving, compliance, and leadership in complex, fast paced environments.

Jonathan holds a Bachelor of Science in Biology from Western Illinois University and is an active member of RAPS, DIA, and the Animal Health Institute. He is known for fostering innovation, developing regulatory talent, and driving high quality outcomes that support global product success.



Dr. Desmond G. Hunt

Sr. Principal Scientist

United States Pharmacopeia (USP)

Quality Matters: The Importance of Particulate Matter in Pharmaceutical Quality

Wednesday 4:15 - 5:00pm

Dr. Desmond G. Hunt has been with USP since 2005 and holds the position of Sr. Principal Scientist in the Compendial Science Group-General Chapters. He works with the Packaging and Distribution and Dosage Forms Expert Committees, where he works to develop and revise USP Standards. He has authored many publications and peer-reviewed articles and is a frequent speaker and instructor on topics related to pharmaceutical packaging, particulate matter in parenteral and ophthalmic dosage forms, and good storage and transportation practices. He participates in several industry Working Groups and Technical Committees related to his areas of expertise. Dr. Hunt obtained his M.S. and Ph.D. from the University of Texas at Austin.





Steven Jones

*Director of Global
Regulatory Affairs CMC*

Boehringer-Ingelheim

WORKSHOP: Update on Animal Health Regulations

Thursday 1:00 - 4:00pm

Steven Jones is an accomplished regulatory affairs leader with over 25 years of experience shaping global compliance strategies in human and animal health pharmaceuticals. As Director of Global Regulatory Affairs CMC at Boehringer Ingelheim Animal Health, Steven oversees international regulatory operations, guiding Chemistry, Manufacturing, and Controls (CMC) strategies that enable timely product approvals and lifecycle management across diverse markets.

Recognized for his ability to navigate complex regulatory landscapes, Steven has led cross-functional teams through high-impact initiatives, managed multimillion-dollar budgets, and built collaborative relationships with health authorities worldwide, including FDA, EMA, USDA, and EDQM. His expertise spans dossier preparation, risk mitigation, and strategic regulatory planning for innovative therapies and complex dosage forms.

Steven holds U.S. Regulatory Affairs Certification (RAC) and has completed advanced global leadership training at IESE Business School. His contributions have earned him Boehringer Ingelheim's prestigious President's Award for excellence in leadership and regulatory innovation.

Steven brings deep insights into regulatory strategy, global compliance trends, and best practices for aligning technical rigor with business objectives in highly regulated environments.



Dr. Margareth R. C. Marques

Senior Principal Scientist

USP

Quality requirements for Ophthalmic Products

Wednesday 3:30 - 4:15pm

Magda Joseph (B. Eng.) Dr. Margareth R. C. Marques is currently Senior Principal Scientist at USP, where she manages documentary standards on dissolution, disintegration, drug release, ophthalmic products and products applied to the skin, osmolality and several instrumental techniques. In addition, she manages databases on reagents, chromatographic columns and dissolution/disintegration tests.

She is an editor and contributor to the Dissolution Technologies journal. She has a bachelor's degree in pharmacy, a M.Sc. in Pharmacy, both by the University of Sao Paulo, Brazil, and a Ph.D. in Analytical Chemistry by the State University of Campinas, Brazil. She has more than 20 years of experience in Quality Control and Quality Assurance both for active pharmaceutical ingredients as well as for pharmaceutical dosage forms.

CONFERENCE FEEDBACK SURVEY

Your input is very important to our planning process.

Please help improve our conference by completing a quick survey online on Thursday following conference adjournment!

Visit bit.ly/gmp-50 or scan the QR Code



SPEAKERS



Marie Mathews

Principal

Franklin Mathews Group

New FDA QMSR Changes for Combination Products and Medical Devices

Wednesday 9:00 - 9:45am

Marie Mathews brings more than 25 years of regulatory expertise to her leadership of Franklin Mathews Group, with a reputation for turning complex FDA requirements into practical, strategic guidance for biopharmaceutical and medical device companies.

Over an 18 year career with the U.S. Food and Drug Administration, she served as an award winning investigator across drugs, devices, and biologics, a field drug and biologics compliance officer reviewing violative inspections and recommending further FDA action. She was then promoted to compliance officer in CDER's Office of Manufacturing Quality, where she often handled especially complex regulatory cases. After leaving FDA, Marie joined Bristol Myers Squibb as Associate Director of GxP External Engagement, helping build a comprehensive compliance and regulatory intelligence program and representing the company in major international industry and trade groups. She has also worked in risk GxP risk management with Emory University and the Centers for Disease Control.

Marie holds both a B.S. and an M.S. in Pharmacy/Regulatory Affairs from the University of Georgia and is a highly rated speaker on FDA policy, compliance, and mature quality cultures, frequently presenting at leading GxP conferences such as ISPE, ASQ, and the UGA/FDA International GMP Conference.



Jessica P. McAlister

Senior Director of Compliance

FDA

The FDA is Coming: Are you Ready? A Proactive Approach to 503b Audit Preparedness

Tuesday 10:45 - 11:30am

Jessica P. McAlister is a seasoned leader in pharmaceutical compliance with more than 14 years of distinguished service at the U.S. Food & Drug Administration (FDA). As the agency's first Pharmacy Compounding National Expert, she played a foundational role in shaping federal oversight of compounding practices and spearheaded the development of the FDA's first Outsourcing Facility Compliance Program—now a cornerstone of regulatory inspections nationwide.

During her tenure at the FDA, Jessica authored and influenced pivotal policies, regulations, and national training programs that strengthened the agency's ability to safeguard public health. Her inspection portfolio includes over 250 domestic and international audits across pharmaceutical manufacturing and compounding sectors, resulting in impactful regulatory actions focused on consumer safety and quality assurance.

In addition to her regulatory leadership, Jessica is a published contributor to medical literature. She recently co-authored a case study published in PubMed examining the use of pravastatin and L-arginine in early-onset, severely growth-restricted dichorionic twin pregnancies within the field of obstetrics and gynecology, reflecting her commitment to evidence-based advancement in maternal-fetal health.

Jessica currently serves as Senior Director of Compliance at Olympia and Wesley Pharmaceuticals, where she leads internal audits aligned with the FDA's Outsourcing Facility Compliance Program and 21 CFR Parts 210 and 211. She collaborates cross-functionally with Quality, Production, and Engineering teams to drive excellence in process validation, cleaning and disinfectant studies, stability programs, and procedural development.

Recognized for her professional impact and leadership, Jessica has been nominated for the Orlando Business Journal's 40 Under 40 Executives for 2026.

She holds a B.S. in Biology from Rollins College and remains deeply committed to advancing pharmaceutical safety, regulatory integrity, and scientific innovation.

SPEAKERS



Alan Minsk

*Partner, Co-Chair of the
Food & Drug Practice Team*

Arnall Golden Gregory LLP

FDA and non-FDA issues to consider with non-compliance beyond 483s and warning letters

Tuesday 1:45 - 2:30pm

Alan Minsk is a partner and chair of the Food & Drug practice at Arnall Golden Gregory LLP, advising pharmaceutical, biologic, medical device, cosmetic, food, and dietary supplement companies on legal and regulatory matters relating to the U.S. Food and Drug Administration. Additionally, Alan counsels life science companies and venture capital firms on regulatory matters involving acquisitions, divestitures, regulatory opinions, co-promotions, and licensing agreements. Recognized nationally and globally by *Chambers & Partners* for his legal work, Alan is a highly sought-after speaker and author in the life sciences industry. He also serves on a number of advisory boards and regularly conducts training webinars and in-house engagements.



Erika Pfeiler, PhD

*Senior Consultant -
Microbiology*

ValSource, Inc.

No Barriers to Success: Modern Technology in Sterile Filling Operations

Tuesday 4:00 - 4:45pm

Dr. Erika Pfeiler is a pharmaceutical microbiologist and ex-regulator with expertise in manufacturing of both sterile and nonsterile products. Dr. Pfeiler currently leverages her technical and regulatory expertise to help clients with a range of issues, including enhancing their aseptic operations in a way to promote patient safety and regulatory compliance. She is passionate about the roles that communication and training play in creating a successful manufacturing environment. Dr. Pfeiler joined ValSource, Inc. in early 2025 after 15 years with the FDA where she worked as a microbiologist in the Center for Drug Evaluation and Research.



Rob Piperno, MS, MBA

Senior Director

Lachman Consultants

Autologous versus allogeneic requirements in cell and gene therapy

Thursday 10:30 - 11:15am

Rob Piperno is a Senior Director at Lachman Consultants with more than 25 years of experience spanning biopharmaceuticals, cell and gene therapy, and global quality leadership. A recognized expert in CGT compliance, CMC strategy, and quality systems, Rob has played a pivotal role in advancing some of the industry's most innovative therapies. His career includes the successful development and launch of a pioneering ex vivo autologous gene therapy—the first of its kind to achieve regulatory approval—an accomplishment that helped shape the evolution of advanced therapeutics.

Rob has led large, multidisciplinary technical and quality organizations through product development, technology transfer, PPQ, and global regulatory inspections. His leadership was instrumental in the successful commercialization of a major biologic therapy, guiding programs from clinical development through full-scale manufacturing and regulatory approval across both drug substance and drug product operations.

Before joining Lachman, Rob held senior roles at Nuevoco, SwanBio Therapeutics, GSK, Johnson & Johnson, and Omnicare, where he built and strengthened quality systems, inspection readiness programs, and global QA oversight. He holds an MBA in Pharmaceutical Marketing from St. Joseph's University and an MS and BA in Biology from Rutgers University.

Rob brings deep technical expertise, regulatory insight, and strategic leadership to every engagement—helping organizations navigate complex challenges in a rapidly evolving therapeutic landscape.

SPEAKERS



Simone Pitts

National Expert Pharmaceutical Investigator Office of Human and Animal Drug Inspectorate

FDA

Case Studies from GMP Inspections

Wednesday 8:15 - 9:00am

Simone Pitts serves as a National Expert Pharmaceutical Investigator in FDA's Office of Human and Animal Drug Inspectorate. With over 30 years of regulatory experience in FDA, her career progression includes positions as a Microbiologist, Domestic Investigator, Foreign Drug Cadre Investigator, and Team Biologics Investigator prior to her current role as National Expert, Pharmaceutical. Ms. Pitts is internationally recognized as a subject matter expert in biologics, pharmaceuticals, and active pharmaceutical ingredient (API) processes. She is regarded as a global industry thought leader in critical inspectional areas, including aseptic manufacturing operations, process validation, and cross-contamination control strategies.

Throughout her distinguished career, Ms. Pitts has developed specialized expertise in conducting and directing highly technical, complex, and multifaceted domestic and international inspections and investigations. Her extensive experience encompasses active pharmaceutical ingredients and finished drug products across diverse categories, including large and small volume parenterals, solid oral dosage forms, vaccines, allergenic extract products, plasma derived products (and their recombinant analogues), licensed IVD products, gene/cellular therapy. Ms. Pitts holds a Bachelor of Science degree in Biology and a Master of Science degree in Microbiology. She also serves as a training resource for the FDA, contributing to the development of agency expertise and capabilities.



Dr. Hans Joachim Ploss

Head of Corporate Quality Audits & Inspections

Boehringer-Ingelheim

The Value of Quality

Tuesday 8:30 - 9:15am

Dr. Hans Joachim Ploss serves as the Head of Corporate Quality Audits & Inspections at Boehringer Ingelheim, and is a member of the Boehringer Ingelheim Global Quality Leadership Team. In his role, he leads the global strategy and execution of corporate audits and self inspection oversight across the company's Human Pharma, Biopharma, Animal Health, Development, and Commercial divisions. He oversees harmonized auditing practices and drives robust inspection readiness to support regulatory compliance across a diverse global manufacturing and quality network. Dr. Ploss frequently collaborates with international stakeholders, industry groups, and external experts to advance innovative quality solutions, including data driven and predictive approaches to inspection readiness. Before joining Boehringer Ingelheim, Dr. Ploss held roles of increasing responsibility at Aventis, Sanofi, and CSL Behring, where he gained broad experience spanning quality control and assurance, global quality systems, and regulatory compliance. His past experience also includes holding a QA leadership role at a site undergoing FDA consent decree remediation. He holds both a master's degree in pharmacy and a Ph.D. in pharmacy from the Julius Maximilians University of Wurzburg.



Commander Mahesh Ramanadham

Deputy Director, Office of Policy for Pharmaceutical Quality Center for Drug Evaluation and Research, Office of Pharmaceutical Quality (OPQ) FDA

Update from the Office of Pharmaceutical Quality

Wednesday 1:15 - 2:00pm

Commander (CDR) Mahesh Ramanadham is the Deputy Director for the Office of Policy for Pharmaceutical Quality, within FDA's Center for Drug Evaluation and Research, Office of Pharmaceutical Quality (OPQ). He joined the FDA in November 2009 after graduating with his Doctor of Pharmacy degree from the University of Maryland and his M.B.A. from the University of Baltimore. Within FDA, he has served in leadership roles in the Office of Compliance and the Office of Pharmaceutical Manufacturing Assessment within OPQ.

Prior to joining FDA, CDR Ramanadham had experience in solid oral dosage manufacturing ranging from OTC products to schedule II narcotics. Outside of FDA, CDR Ramanadham continues to practice pharmacy in the community setting to maintain perspective on the clinical relevancy and impact of FDA's efforts in pharmaceutical quality.

SPEAKERS



Dr. James Marshall Shepherd

*Associate Dean,
Georgia Athletic Association
Distinguished Professor
of Geography and
Atmospheric Sciences*

University of Georgia

Dinner Speaker: Multiple Perspectives on Extreme and Compound Weather Events

Tuesday 6:00 - 8:00pm

Dr. J. Marshall Shepherd is a leading international weather-climate expert and is the Georgia Athletic Association Distinguished Professor of Geography and Atmospheric Sciences at the University of Georgia. In 2025, Dr. Shepherd was appointed as Regents Professor, the highest professorship bestowed by the University System of Georgia. Dr. Shepherd was the 2013 President of American Meteorological Society (AMS), the nation's largest and oldest professional/science society in the atmospheric and related sciences. Dr. Shepherd serves as Director of the University of Georgia's (UGA) Atmospheric Sciences Program, and Full Professor in the Department of Geography. He also serves as Associate Director of Climate and Outreach for the Institute for Resilient Infrastructure Systems and holds a joint appointment within the College of Engineering.

In 2023, he was selected as the inaugural Associate Dean for Research, Scholarship and Partnerships in the Franklin College of Arts and Sciences, the University of Georgia's largest college. He also holds a joint appointment with the U.S. Department of Energy, Savannah River National Laboratory. His areas of research include urban climate, hydrometeorological extremes, weather-climate risk, and innovative outreach strategies. He has secured several million dollars in extramural funding to support his research.



Howard Sklamberg

Partner at Arnold & Porter

The Use of AI in FDA GXP Compliance and Drug Approval

Tuesday 1:00 - 1:45pm

Howard Sklamberg counsels clients on a wide range of compliance and enforcement issues related to U.S. Food and Drug Administration (FDA) regulation and policy. His experience is rooted in a deep understanding of U.S. and foreign food, drug, and medical devices law and policy, and is able to guide domestic and international clients through the regulatory challenges they face. Areas of focus include inspections and warning letters, investigations, civil and criminal enforcement and litigation, medical product applications and clinical research, food and hemp regulation, imports, the development of FDA policy and FDA-related legislation, and business transactions involving FDA-regulated companies. Howard is also a litigator and represents FDA-regulated companies and individuals in criminal and civil investigations, discovery, and trial.

Prior to entering private practice, Howard held a variety of roles at FDA from 2010 to 2017, including Deputy Commissioner for Global Regulatory Operations and Policy; Director of the Office of Compliance, Center for Drug Evaluation and Research; Deputy Associate Commissioner for Regulatory Affairs; and Director in the Office of Enforcement. While at the agency, he directed an office of over 5,000 employees in more than 200 offices, laboratories, and import facilities across the United States, Asia, Europe, and Latin America. As Deputy Commissioner, Howard was FDA's top enforcement official. He oversaw the agency's inspections, enforcement, recalls, and import operations programs.

SPEAKERS



Kelly M. Smith

Dean, UGA College
of Pharmacy

University of Georgia

Welcome

Tuesday 8:00 - 8:30am

Kelly M. Smith is Professor and Dean of the University of Georgia College of Pharmacy. Serving as the first female dean in the College's 120-year history, she has led the College to a significant ascension in its profile, with a 2024 U.S. News and World Report rank of 15 among the more than 140 U.S. colleges of pharmacy in the nation. An alumna of the College, she graduated in 1992 with a B.S. in Pharmacy and in 1993 with a Doctor of Pharmacy and completed postgraduate residency training in drug information at UFHealth Jacksonville (Florida). Dr. Smith began her career at University of Kentucky Healthcare as a drug information pharmacist, where she later served as Director of both the Postgraduate Year One Residency training program and the Drug Information Center. Deepening her engagement in academia led to faculty experiences in both the clinical and tenure tracks at the University of Kentucky College of Pharmacy, as well as roles as Director of Residency Program Advancement, Associate Dean for Academic and Student Affairs, and Interim Dean.

A leader with a record of advancing practice and pharmacy education, Dean Smith is a past President and Fellow of the 65,000-member American Society of Health-System Pharmacists (ASHP), one of the largest pharmacy membership organizations in the world. She currently serves as Chair of the Board of Directors of the ASHP Foundation, the philanthropic arm of the organization. She also is a Fellow of the American College of Clinical Pharmacy and serves on the American Association of Colleges of Pharmacy Transformation Center Expert Advisory Council. She is a past recipient of the Zeta Tau Alpha Foundation's Outstanding Alumna Award in recognition of her national leadership in Pharmacy and Pharmacy education.

OFFERING ONLINE GRADUATE PROGRAMS SINCE 2005:

- ✓ Regulatory Sciences Master's Degree
- ✓ Clinical Trials Management Master's Degree
- ✓ Regulatory Sciences Certificate
- ✓ Clinical Trials Certificate
- ✓ Drug Safety & Pharmacovigilance Certificate
- ✓ Chemistry, Manufacturing, & Controls Certificate

SCAN QR CODE
TO LEARN MORE



For further information,
rxsciences@uga.edu or rx.uga.edu.



UNIVERSITY OF
GEORGIA
College of Pharmacy

SPEAKERS



Dr. Ivy Sweeney

*Deputy Program Director,
Office of Human and Animal
Drug Inspectorate (OHADI)
within the Office of Inspections
and Investigations (OII)*

FDA

The FDA Drug Inspectorate Updates

Tuesday 10:00 - 10:45am

Dr. Ivy Sweeney currently serves as the Deputy Program Director of the Office of Human and Animal Drug Inspectorate (OHADI) within the Office of Inspections and Investigations (OII) in the U.S. Food and Drug Administration (FDA). In this capacity, she provides leadership for domestic and foreign pharmaceutical quality inspectional operations, working in conjunction with the Program Director, FDA's Center for Drug Evaluation and Research (CDER), and the Center for Veterinary Medicine (CVM). She oversees operational functions including inspections and investigations, sample collections, compliance, and enforcement activities for the pharmaceutical field divisions and the foreign inspection program.

Over the course of her career, Dr. Sweeney has held multiple senior leadership roles within FDA including Acting Director in OHADI, Acting Office Director and Deputy Office Director in the Office of Human Food Inspectorate (OHFI) within OII, and Deputy Program Director in the Office of Human and Animal Food Operations (OHAFO) East within the Office of Regulatory Affairs (ORA). In addition, she has experience in a variety of other FDA positions including Branch Director, CDER Scientist, Drug Investigator, Compliance Officer, and Supervisor.

Dr. Sweeney began her public health career with the U.S. Department of Labor in 2009, where she held leadership positions including Assistant Area Director and Compliance Safety & Health Officer. Prior to federal service, Dr. Sweeney worked as a Senior Manager in industry, supervising scientists and overseeing work activities related to pre-formulation and de-formulation of dietary supplements and drug products, drug product development, analytical testing and method development, budgeting, work plan formulation, and quality program development.

Dr. Sweeney holds dual Bachelor of Science degrees in Chemistry and Biology from Barry University and a Doctor of Philosophy degree in Chemistry from the University of Miami. With more than 20 years of leadership experience spanning academia, industry, and the federal government, Dr. Sweeney brings extensive technical expertise, collaborative skills, and executive management capabilities to address critical public health challenges.



Dr. Lauren Zaleski

*Associate Manager,
Regulatory Affairs*

Boehringer-Ingelheim

WORKSHOP: Update on Animal Health Regulations

Thursday 1:00 - 4:00pm

Dr. Lauren Zaleski earned her undergraduate degree in biology as well as her Doctorate in Veterinary Medicine at the University of Georgia. Following graduation in 2004, Dr. Zaleski spent 15 years practicing veterinary medicine in the metropolitan Atlanta area. During this time, she worked as a small animal private practice veterinarian and oversaw a diverse range of both surgical and medical cases.

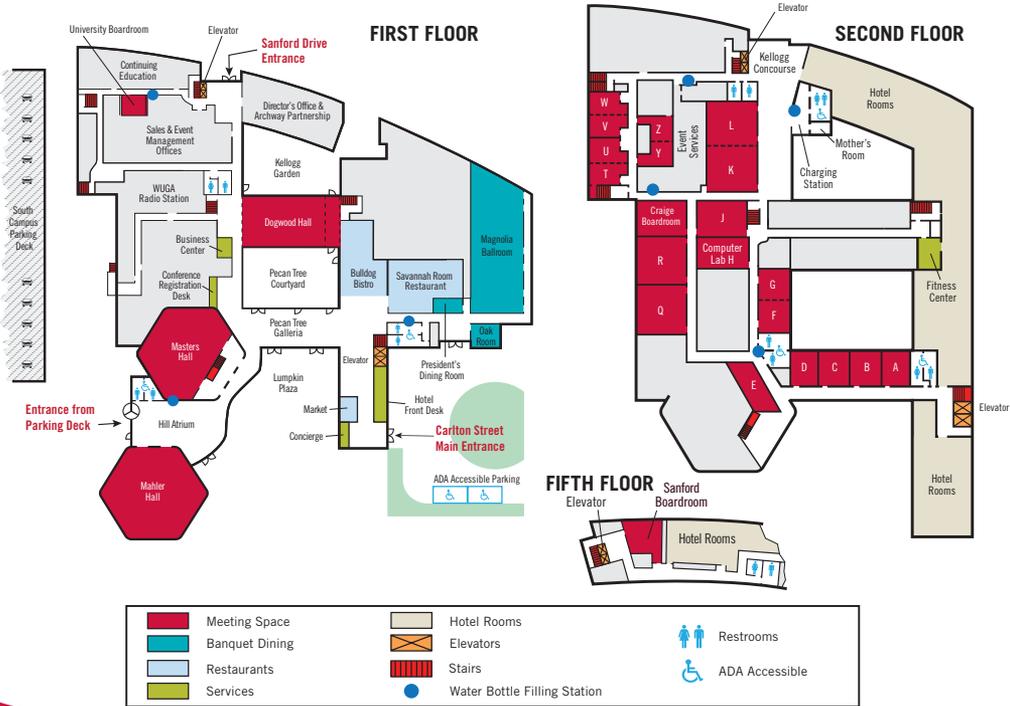
Following her extensive clinical career, Dr. Zaleski shifted her professional focus to the Animal Health industry. In 2019, she joined Boehringer Ingelheim, working in Regulatory Affairs. Her current role focuses on post-licensure activities, including supporting product geo-expansions, overseeing technology transfers, managing claim extensions, and collaborating with the Quality team on compliance topics.

Her professional interests include the prevention and management of high consequence emerging and transboundary diseases such as African Swine Fever and Foot and Mouth Disease. She also serves as a Campus Ambassador in a collaboration between Boehringer and the University of Georgia. Through this partnership, she is dedicated to promoting awareness of the diverse career opportunities available within both the Animal Health and Human Health Industries.

GEORGIA CENTER MAPS & INFO



FACILITY MAP



GEORGIA CENTER MAPS & INFO

AMENITIES & INFORMATION

ON-SITE DINING

Bulldog Bistro is open every day from 7 a.m. to 10 p.m. and offers casual breakfast and lunch options, including grab-and-go sandwiches, salads, and snacks. Throughout the day, the Bistro serves locally-roasted Jittery Joe's coffee, specialty coffeehouse drinks, and homemade pastries. In the evenings, enjoy small plates and our full bar either inside the Bistro or in the adjoining Pecan Tree Courtyard — complete with fire pits.

The Savannah Room Restaurant provides a relaxed, full-service atmosphere for weekday lunches and dinner every evening. Lunch is offered from 11 a.m. to 2 p.m., and dinner is served from 5 to 9 p.m.

The Market, open 24 hours, has a selection of snacks and drinks for guests on the go. Simply select your items and bring them to the hotel's front desk.



TRANSPORTATION

Complimentary shuttles are available on request at the concierge desk, transporting guests anywhere within a 3-mile radius. Guests are also welcome to use the university bus system, which has a stop just outside, to travel around our campus. For attendees traveling longer distances, our building is a stop for an hourly shuttle to and from Atlanta's Hartsfield-Jackson International Airport, operated by Groome Transportation.

Atlanta Hartsfield-Jackson Airport Transportation:

- Groome Transportation..... 706-612-1155

Local Transportation:

- Athens Cab Service..... 706-543-5646
- United Taxi 706-549-0808
- Georgia Center complimentary shuttles
- University of Georgia Bus Service
- Uber/Lyft also available



BUSINESS CENTER

The Business Center is located on the first floor close to the Conference Registration desk. It is open 7 a.m. to 7 p.m. for guests attending events. Hotel guests have 24-hour access with their hotel keycard.

COMPLIMENTARY WI-FI

1. Join the Wi-Fi network named "Georgia Center Guest."
2. Enter your mobile phone number and agree to the terms & conditions.
3. Once you receive a login code on your SMS-enabled device, enter your code on the Wi-Fi network landing page.
4. Open your internet browser and navigate to any website.



1197 S Lumpkin St, Athens, GA 30602
(706) 548-1311 • georgiacenter.uga.edu

MS5385

CONNECT WITH US



Conference hashtags:
#GMP2026 **#50YearsOfGMP**

rx.uga.edu

**SAVE THE
DATE**



**UNIVERSITY OF
GEORGIA**
College of Pharmacy



51st International GMP Conference
March 8 – 11, 2027 - Athens, GA



Bulldog Print + Design
Finance & Administration
UNIVERSITY OF GEORGIA

Proud to provide graphic design
and printing services for this event.