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29TH ANNUAL

GMP BY THE SEA

AUGUST 11 – 13, 2025 | CAMBRIDGE, MARYLAND

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About the Conference

Although the longstanding **GMP by the Sea** conference is in its 29th year, this may be the most important year to attend to ensure you are informed regarding recent regulatory transitions. Attending the conference presents an incredible opportunity to gain in-depth insights into regulatory updates, technological advancements, and how to navigate GMP and manufacturing challenges in the biopharmaceutical industry.

Key highlights from the conference include an update and current initiatives to be shared by United States Food and Drug Administration (FDA) confirmed CDER Deputy Director. Also former regulators will share FDA changes and industry impact, plus an inspectional perspective.

Valuable updates are also scheduled to be presented regarding FDA's Quality Management Maturity and quality culture initiatives. Discussions on domestic and international regulatory trends and tools, as well as their impact on manufacturing and inspections, will accompany presentations.

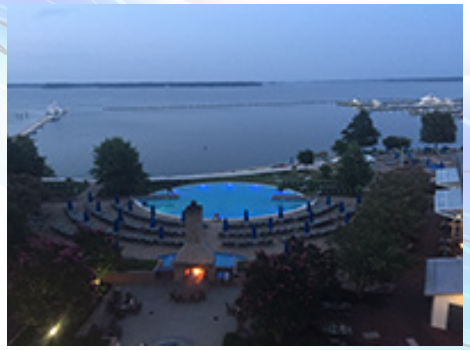
Advanced technology, such as applications of AI and machine learning across product lifecycles and how it may support regulatory assessment and inspection, will be highlighted by industry experts. Focused discussions will be held regarding how to optimize tools to apply and maintain quality oversight, as well as interactive technology demonstrations.

Workshops held during the conference will cover a variety of timely topics, such as sustainable manufacturing practices, effective communication strategies with regulatory health authorities, data integrity, aseptic manufacturing/contamination control, and preparing for health authority inspections.

This year we are having a special question and answer session to close out the conference titled *Ask Former Regulators Q&A Panel*. Bring your questions and hear from this panel of experts made up of recent regulators from FDA.

As always, there will be plenty of networking opportunities to connect with speakers and other conference attendees in a stunning conference setting!

We hope you will join us for this informative and beneficial event!



About the Conference

Who Should Attend?

- Anyone involved in FDA inspection preparation, hosting, or responses including production, quality assurance, quality control, regulatory affairs, or auditing in the pharmaceutical and biopharmaceutical industry in Regulatory and GMP matters.
- Supervisory personnel and managers can enhance Regulatory and GMP performance by sending production, quality, and regulatory personnel to this learning experience. They will gain a significant appreciation of FDA's inspectional approach, and they will learn the critical skills needed to prepare for and properly host inspections.
- Anyone who wants an exceptional GMP learning experience and a fun time

Why Attend?

- To gain a better understanding of how the Regulatory Authorities look at your operations and how to anticipate problem areas before they create problems for your company during the inspection
- To take advantage of the knowledge of seasoned FDA and industry experts who have "been there and done that"
- To obtain current information about FDA activities
- To get those cGMP questions that cause you sleepless nights answered by the experts

Attendees have high praise for the conference:

"It's the best conference for GMPs. Information you can't get anywhere else."

"Great conference! Thank you for the organization."

"I really enjoyed the Tuesday morning moderated session, especially the overview on AI/ML and the connection to Part II. Learned a lot about QMM."

"Really enjoy the relaxed, friendly feeling of this conference."

"All the presenters were awesome!!!"

About the Venue

Located on the scenic Eastern Shore of Maryland, the Hyatt Regency Chesapeake Bay Golf Resort, Spa and Marina is the area's finest full-service, year-round resort. Built on over 342 acres, the 400 room resort features an 18-acre nature preserve with guided hikes and wildlife observation, an 18,000 square foot European Health Spa, a glass-enclosed pool and lounge area, an 18-hole Keith Foster designed championship golf course, and a 150-slip marina.

Cambridge, Maryland is 79 miles southeast of BWI Airport, 90 miles southeast of Ronald Reagan Washington National Airport, and 117 miles southeast of Dulles. For exact directions to the hotel, please log on to https://chesapeakebay.regency.hyatt.com/en/hotel/our-hotel/map-and-directions.html

Reservations:
Online: GMP BY THE SEA - PHARMA CONFERENCE (hyatt.com)
OR
https://www.hyatt.com/en-US/group-booking/CHESA/G-GMSE

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About the Speakers

Maria Amaya, PhD – Dr. Amaya is the Lead External Advocacy, North America in Quality Policy & Advocacy at Roche. In this position, she works within the Roche/Genentech Global External Advocacy community to develop and deliver innovative quality and current GMP regulatory pathways and collaborate with internal and external stakeholders, including support in harmonization and streamlining of regulations. Dr. Amaya has more than 15 years of experience in the pharmaceutical industry working in product development, manufacturing technology, regulatory, and quality, and compliance. She holds a PhD in protein chemistry, a Master of Science in protein engineering from the Paris-Sud University in France, and a Bachelor of Science in chemistry from the National University in Colombia.

Deb Autor, JD – Ms. Autor is CEO of Healthcare Innovation Catalysts. She leads a multidisciplinary team of ex-FDA, industry, and academic experts that combines strategic and technical expertise in regulatory affairs, clinical, quality, compliance, reimbursement, and federal partnerships. Ms. Autor has over 30 years of experience in regulatory, compliance, legal, and business strategy, including serving as Deputy Commissioner of the FDA, Director of Compliance at FDA/CDER and leading global regulatory and quality functions at AstraZeneca and Mylan. Before FDA, she was a Trial Attorney at the U.S. Department of Justice, where she prosecuted dozens of civil and criminal cases on behalf of FDA. She is Chair of the FDA Alumni Association, and an expert advisor, board member, and decorated government leader educated at Harvard, Kellogg, BU, and Columbia.

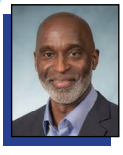
Sarah Barkow, PhD – Dr. Barkow is the Senior Director of Proactive Compliance & Innovation at AstraZeneca. In this role, she spearheads initiatives to enhance regulatory compliance and drive innovative solutions. Dr. Barkow's expertise in GxP regulatory surveillance and external engagement ensures AstraZeneca's adherence to global standards and fosters proactive compliance strategies. Prior to AstraZeneca, she was the Director of GxP External Engagement at Bristol Myers Squibb and served as a Senior Advisor and Acting Director at the FDA's Office of Compliance. Dr. Barkow's contributions include drafting key guidance and policy documents, as well as inspectional compliance programs. She also has a background in immunoassay development from Beckman Coulter.

Ileana Barreto-Pettit, RN, MPH – Ms. Barreto-Pettit is President of Capitana Audit Solutions. She previously held the position of Vice President – Technical, Strategic Compliance Consulting at Parexel International for a period of 18 months. During her tenure, she led numerous audits to help pharmaceutical companies globally prepare for FDA inspections. Additionally, she provided crucial behind-the-scenes support during inspections and assisted with remediation efforts. Ms. Barreto-Pettit held several roles in her 24 years of work experience at the US FDA, with her most recent position being Drug National Expert in the Office of Regulatory Affairs. She conducted hundreds of domestic and international inspections and provided inspectional and technical assistance to field and foreign offices on complex pharmaceutical inspections and regulatory matters. Ms. Barreto-Pettit was an FDA trainer for 17 years, training hundreds of new drug investigators, compliance officers, chemists, microbiologists, and drug application reviewers on the federal drug regulations and inspectional process.

Jennifer L. Bragg, BA, JD – Ms. Bragg is Partner, Latham & Watkins LLP, and is a nationally recognized lawyer advising US Food and Drug Administration (FDA) regulated companies facing complex legal and regulatory challenges, government investigations, and related litigation. She draws on more than two decades of experience, including as Associate Chief Counsel for Enforcement in the FDA's Office of Chief Counsel, to advise companies and boards of directors and develop commercially focused strategies for clients to resolve regulatory issues, minimize litigation and enforcement risks, and overcome transactional hurdles. She counsels boards and compliance departments on corporate compliance program development and other protective measures designed to mitigate the risk of litigation.

Tamika D. Cathey, BS – Ms. Cathey is Global Principal Technical Lead, Pharma Biotech Dietary Supplement Consulting & Life Sciences at NSF. She is a Subject Matter Expert with 20+ years of regulatory enforcement, regulatory compliance, and Quality Management experience. Her previous tenure with the U.S. Food & Drug Administration as a Consumer Safety Officer built a proficiency in regulatory inspections, FDA compliance, CAPA remediation, and enforcement action under FDA 483, Warning Letters, and Consent Decree. As an Industry Consultant, she has supported industries in sterile and non-sterile Pharmaceutical, Active Pharmaceutical Ingredients (API), Dietary Supplements, Biologics, Tobacco and Medical Device. Ms. Cathey specializes in FDA Inspection Readiness, Project Management, Quality System Design, product release and commercialization, cGMP and GCP auditing, lead auditor and risk management training, strategic planning, gap assessments, and FDA 483s, Warning Letters and Consent Decrees removal.

Barry Cook, BS – Mr. Cook is a dynamic and visionary Vice President of Quality Assurance and Regulatory Affairs. He has a proven track record of driving regulatory excellence, operational transformation, and cultural modernization. Mr. Cook is an expert in international regulations, quality management systems (QMS), product lifecycle management, inspection readiness, and post-market surveillance and adept at leveraging strategic foresight and industry expertise to implement innovative processes that ensure compliance, mitigate risk, and support sustainable business growth. He is known for inspiring high-performing teams, delivering clarity in complex situations, and building compliance-driven cultures that thrive in evolving global markets. Mr. Cook is also experienced in navigating resource-constrained environments to achieve organizational success while fostering collaboration and innovation.



Alonza Cruse, BS – Mr. Cruse is the former Director of the Office of Human & Animal Drug Inspectorate within the Office of Inspections & Investigations (OII) in the Food and Drug Administration (FDA). The office is responsible for all pharmaceutical quality inspections and investigations, working in conjunction with FDA's Center for Drug Evaluation & Research and the Center for Veterinary Medicine. From 2013 to 2015, he served as the acting director of the Office of Medical Products & Tobacco Operations within ORA, overseeing activities such as implementation of the Generic Drug User Fee Amendments, pharmacy compounding, and the development of a new inspection protocols program. Prior to that, Mr. Cruse was the director of the Los Angeles District Office, where his responsibilities included providing executive leadership to implement, manage and evaluate FDA's regulatory operations. Mr. Cruse first joined ORA in 1983 as a microbiologist. He received his Bachelor of Science degree in medical technology from York College (City University of New York).

About the Speakers

Robert Darius, BS – Mr. Darius is the Head of Quality Rare Disease, Oncology & Immunology at Sanofi. Previously, he served as Senior Vice President of Quality at Novavax Vaccines. Prior to that, Mr. Darius was Vice President of the Global Quality Unit in GSK Vaccines for North America and Germany for 11 years. He served for 15 years in the US FDA Center for Biologics Evaluation and Research, Division of Manufacturing and Product Quality, as Lead Reviewer & Inspector and also served as Special Assistant on Counter Bioterrorism issues, reporting to the CBER Director. Mr. Darius is a Microbiologist by training and graduated from George Mason and Johns Hopkins Universities.

Maya M. Davis, PhD, MPH – Dr. Davis is a Senior Vice President of Regulatory Compliance at Eliquent Life Sciences, helping clients align their approach with FDA's regulatory expectations to gain and maintain market authorization. Prior to that, she served 16 years with the FDA in ORA as an Investigator, Drug Specialist, Pre-Approval Manager, Compliance Officer, Mutual Recognition Senior Program Expert, and in CDER as a Senior Consumer Safety Officer in the Office of Quality Surveillance. Dr. Davis also held details as Acting Branch Chief of Foreign Inspections, Acting Director of Compliance Branch, and Supervisory Investigator.

FDA

Michael Davis, MD, PhD – Dr. Davis is a Deputy Director at the FDA Center for Drug Evaluation and Research (CDER), bringing extensive regulatory and clinical expertise to pharmaceutical development and manufacturing oversight. He previously served as Clinical Team Leader in CDER's Division of Psychiatry (2016-2022), receiving multiple FDA honors including the Outstanding Service Award. From 2022-2025, Dr. Davis was Chief Medical Officer at Usona Institute, developing psychedelic therapeutics. He holds an MD and PhD in Pharmacology from Case Western Reserve University and completed psychiatric residency at UCLA.

Lynne Ensor, PhD – Dr. Ensor is the President and Owner of Ensor Pharma Biotech Consulting, providing strategic regulatory consulting to the pharmaceutical and biotechnology sectors. She is a seasoned expert in sterile product manufacturing, regulatory affairs, compliance, and remediation. Currently, Dr. Ensor is a member of the U.S. Pharmacopeia's Microbiology Expert Committee. Her previous consulting experience includes having served as the Senior Global Managing Director for Pharma Biotech Consulting and Life Sciences Training at NSF International, as well as a Senior Vice President and the Head of Global Compliance Consulting at Parexel International. Prior to consulting, Dr. Ensor served for 21 years at the U.S. Food and Drug Administration (FDA) in the Center for Drug Evaluation and Research (CDER). She served as the Deputy Office Director in the Office of Process and Facilities (OPF)/Office of Pharmaceutical Quality (OPQ), on the senior leadership teams in OPQ and Office of Generic Drugs (OGD), as the Director for OGD/Office of Pharmaceutical Science/OPF's Divisions of Microbiology, and as a CDER Regulatory Master Reviewer. Her prior experience also includes Roche Biomedical Laboratories, the Discovery Channel, and the University of Maryland's School of Medicine. Dr. Ensor earned a B.S. in Biology and a Ph. D. in Microbiology from the University of Maryland.

Tala H. Fakhouri, PhD, MPH – Dr. Fakhouri is the Vice President Consulting, AI & Digital Policy, Real-World Research, at Parexel. Previously, she was Associate Director for Data Science and AI at the FDA's CDER, leading AI policy efforts in drug development. In her recent FDA role, she led the development of the first draft CDER AI Guidance, established the CDER AI Council, and contributed to real-world evidence and digital health technologies policies. Dr. Fakhouri also served as Senior Health Scientist and Chief Statistician for CDC's NHANES, focusing on epidemiologic and statistical issues. Her career includes roles as CDC Epidemic Intelligence Service Officer and deputy lead for health surveys at ICF International. She has authored numerous government reports and peer-reviewed publications. Dr. Fakhouri holds a PhD in Oncological Sciences from the University of Utah, an MPH from Johns Hopkins, and completed a postdoctoral fellowship at Harvard University. She earned her BSc in Medical Technology from Jordan University of Science and Technology.

Charles Gibbons, National Diploma, IT Leadership & Management IS, MIT Sloan + CSAIL AI – Mr. Gibbons is Director, Data Integrity & Data Governance at Lachman Consultants with nearly 30 years of experience in the pharmaceutical industry with expertise in Auditing, Quality Assurance, Data Integrity, Information Technology, PAI inspections and Project Management. He is a Compliance and Auditing Professional who has been responsible for auditing manufacturing operations, commercial affiliates, key suppliers, and third-party manufacturing. Mr. Gibbons has also supported manufacturing sites by completing assessments and providing support for external regulatory agency inspections. He has provided leadership for auditing professionals. Mr. Gibbons developed audit schedules to ensure audits were consistently executed for all supplier types, such as, Third Party Manufacturers, Active Pharmaceutical Ingredients, Contract Laboratories, Logistics and Warehousing, excipients, commodities, medical device, and combination products. He is a founding member of the APIC/CEFIC Data Integrity Task Force and co-author of revision one and two of the APIC/CEFIC Practical risk-based guide for managing Data Integrity.

Tammy Hanley, BBA, MA – Ms. Hanley is Global Quality Auditor (GQA) for Sanofi, with a focus on GxP and Digital areas. She joined Sanofi in November 2002 as a Senior Quality Systems Analyst and Part 11 Project Manager. Over the years, she has held numerous positions in Quality and Digital Compliance. For the past six years, Ms. Hanley has been an integral part of the GQA team, where she has made significant contributions in various areas including auditing digital systems, medical devices and sites for computerized system compliance, mentoring colleagues in computerized systems, collaborating on the development of remote audit methodology during the pandemic for business continuity, and providing support for regulatory inspections through mock audits or back-room assistance. In 2024, she was selected to join the Steering Committee of the ISPE Boston Good Automated Manufacturing Practices (GAMP) Community of Practice (CoP). Her expertise and dedication to the fields of Computer System (CS) Validation, Compliance, and Data Integrity (DI) have been widely recognized.

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About the Speakers

Kir Henrici, BS – Ms. Henrici, CEO, The Henrici Group (HG), has been consulting domestically and internationally for 15 years in support of quality and compliance, with specialized focus and expertise in the areas of Digital Transformation and emerging technologies such as AI/ML, Quality Management Systems (QMS), and Data Governance/Data Integrity Assurance. She has gained a diverse global perspective and working knowledge of quality, compliance and technical challenges and solutions impacting companies around the world, supporting a range of initiatives including QMS design and remediation, and global/site data governance programs.

Brooke K. Higgins, BS, MS – Ms. Higgins is a Senior Vice President for Regulatory Compliance at Eliquent Life Sciences. In this role, she provides strategic guidance on issues related to drug product manufacturing, quality, and regulatory compliance and supports clients to achieve their quality goals. Prior to joining Eliquent, Ms. Higgins served 23 years with FDA, working in both the field and the Center for Drug Evaluation and Research (CDER). She spent 11 years with the Office of Manufacturing Quality at CDER, where she held roles of increasing responsibility, including Senior Policy Advisor, Acting Team Lead and Branch Chief. Ms. Higgins was responsible for reviewing both international and domestic cases, supporting regulatory and enforcement actions, and providing training to investigators and compliance officers. Prior to joining CDER, she spent 12 years with the Office of Inspections and Investigations (formerly ORA), where she began her career as an Investigator and later advanced to serve as a Pre-Approval Manager. While working as the Pre-Approval Manager, Ms. Higgins continued leading domestic and international drug manufacturing inspections, became a member of the Pharmaceutical Inspectorate, and was a Level II drug certification auditor. Ms. Higgins received a MS in Food Science, focusing on food microbiology, and a BS in Biology from Virginia Tech.

Brett Howard, PhD, JD – Dr. Howard is a Senior Director of US Regulatory Policy at the US Pharmacopeia, where he manages USP's regulatory efforts concerning pharmaceutical quality, covering both large and small molecules. Before joining USP, he spent the previous decade working for chemical and pharmaceutical trade associations, developing and implementing advocacy strategies related to chemical exposure, sustainability, nitrosamines, and microplastics, among others. Dr. Howard also spent several years as a patent litigator at a boutique IP firm in the DC area. He has a PhD in organic chemistry from UC Irvine (2009) and a JD from the University of Maryland (2012).

John M. Hyde, BS, BBA, MS – Mr. Hyde is a pharmaceutical engineering and regulatory compliance expert with over 40 years of experience designing and qualifying pharmaceutical manufacturing equipment systems for cGMP operations. He is currently the Founder and Principal at Hyde Emeritus LLC, a consulting firm that provides expert services to pharma and biopharma manufacturers and legal entities, including engineering, and cGMP regulatory consulting and expert witness work. He also is the Founder and a Senior Principal at Hyde Engineering + Consulting, Inc., a boutique biopharmaceutical engineering firm focusing on process equipment design and integration for cGMP manufacturing facilities. Mr. Hyde's regulatory compliance experience includes manufacturing facility pre-inspection auditing and preparation, "back room" support during PAI and routine GMP inspections, and post inspection response report generation and remediation planning. He has specific and in-depth expertise in biopharmaceutical manufacturing systems, cleaning (CIP), and sterilization (SIP).

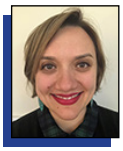
David Jaenisch, BS – Mr. Jaenisch is Principal Machine Learning Engineer with Prompting Integration and Consulting LLC from San Diego where he does generative AI consulting. He has 14 years of experience as a software engineer focusing on AI integration, including five years at a big tech company. Mr. Jaenisch has worked with biotech companies and non-profits, particularly in the GMP space. He specializes in running AI safety and validation workshops and in the development of generative and vision-based AI tools for clients.

Jennifer Kang, JD – Ms. Kang is Senior Director, Corporate Counsel, at Otsuka America Pharmaceutical, Inc., where she leads a team in providing strategic legal and regulatory counsel across the company's R&D lifecycle to optimize the discovery, development, and commercialization of new medications and therapies to advance scientific knowledge and improve patient outcomes. Her practice focuses on working closely with her R&D business partners on various regulatory matters ranging from early asset and clinical development, evidence and real-world data generation, quality management and pharmacovigilance systems, FDA inspections and interactions, transactional negotiations, stakeholder engagement, and post-market activities. Before joining Otsuka, Ms. Kang served as Associate Chief Counsel in FDA's Office of the Chief Counsel (OCC), where she worked closely with federal agencies on enforcement and defensive matters spanning across product centers with a particular focus on cGMP compliance. Prior to her time at FDA, she worked in private practice representing pharmaceutical companies, healthcare systems, and executives in regulatory inquiries, government investigations, and litigation, related to FDA, FCA, FCPA, and other healthcare and white-collar criminal defense matters.

Ted Lis, BS, JD – Mr. Lis uses his legal and engineering training to counsel clients whose manufacturing processes are subject to cGMP regulations. As Counsel, Pharmaceuticals and Biotechnology Enforcement and Compliance at Hogan Lovells LLP, he has assisted clients in resolving cGMP regulatory issues pertaining to API, aseptic injectables, biologics, combination products, ophthalmic products, oral solid doses, medical devices, vaccines, and other regulated products. Mr. Lis assists clients with managing communications with regulatory agencies, preparing for site inspections, and conducting internal investigations. He is currently convenor for the working group revising ISO 14644-5, Cleanrooms and associated controlled environments —Part 5: Operations.

Tim Marini, BS, eMBA – Mr. Marini is Vice President at Baxter Healthcare, leading operations and integrated supply chain for the Medical Products and Therapies Segment. He drives operational excellence through digital transformation, automation, and talent development, advancing Baxter's mission to save and sustain lives.

About the Speakers



Julia Marré, PhD – Dr. Marré is Regulatory Affairs Principal Consultant at NSF with expertise in pharmaceutical and biologic manufacturing and regulatory compliance. She brings senior-level experience as a reviewer at the U.S. Food and Drug Administration (FDA) and as the regulatory lead for drugs, biologics, and combination products. Dr. Marré has a proven track record of leading industry-regulator interactions, leveraging deep regulatory knowledge to drive successful outcomes. With experience as both an FDA reviewer and industry expert, she serves as a trusted advisor in navigating complex regulatory landscapes.

Christopher T. Middendorf, BS, MS – Mr. Middendorf is Senior Director, Technical, Pharma and Biotech GxP Compliance for Hogan Lovells, LLP. He has over 20 years of experience with FDA. He conducted numerous inspections around the globe and was stationed at FDA's Beijing Office for 3.5 years. His last position at FDA was Senior Policy Advisor in CDER's Office of Compliance. After FDA, Mr. Middendorf joined Hogan Lovells, LLP as Director of Pharmaceutical Regulatory Affairs and GMP Compliance where he focused on remediating FDA enforcement actions and co-developed a methodology for evaluating client quality maturity. After Hogan, he joined Parexel as a VP, Technical, Strategic Compliance. During his time at Parexel, Mr. Middendorf focused on getting BLAs to market and remediating negative PLI outcomes in aseptic manufacturing. He re-joined Hogan Lovells in 2024 and focuses on remediating FDA enforcement issues and expanding the use of QMM (Quality Management Maturity) as a business efficiency tool.

Christine M.V. Moore, PhD – Dr. Moore is Executive Director at Organon, Global Quality Compliance. She started as an API process development engineer at Searle/Pharmacia/Pfizer, then moved to US FDA where she led offices responsible for new drug and manufacturing process assessment. In 2016, Dr. Moore returned to industry to advance regulatory policy at Merck and Organon. She is a global thought leader in scientific and regulatory approaches for advancing pharmaceutical manufacturing technologies. She holds a PhD in chemical engineering from MIT and a BS from Northwestern University.

Jeff W. Orlov, BS, mini-MBA – Mr. Orlov is Senior Director of Compliance Enabling QMS within Bristol Myers Squibb Global Quality overseeing the Governance Controls pillar housing key quality systems within the QMS framework. He is responsible for ensuring the implementation and sustainability of fit for purpose processes within the quality systems space. Mr. Orlov has extensive GMP/GDP compliance knowledge and is an expert in process optimization and efficiency having worked in large BioPharma organizations (manufacturing and quality) for over 27 years.

Erika Pfeiler, PhD – Dr. Pfeiler is Senior Consultant – Microbiology with ValSource, Inc. where she 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 a pharmaceutical microbiologist with expertise in pharmaceutical and biopharmaceutical manufacturing of both sterile and nonsterile products and is passionate about the roles that communication and training play in creating a successful manufacturing environment. Dr. Pfeiler previously was a microbiologist and Unit Supervisor in the FDA, CDER Office of Pharmaceutical Quality, Office of Process and Manufacturing Assessment. She was with FDA, CDER for 13 years.

Ranjith Ramakrishnan, MS – Mr. Ramakrishnan is the Head of Quality Assurance (Biologics) within Syngene International Limited, overseeing the QA operations for the Biologics business. He is responsible for ensuring the implementation and sustainability of Quality systems for manufacturing, QC labs (Analytical and Microbiology), vendor management, engineering, and warehousing operations. Mr. Ramakrishnan has extensive GMP/GDP compliance knowledge and is a seasoned professional in QC Lab Operations, multi-geographic deployments of QC/QA systems, operational excellence and digitalization having worked in large BioPharma organizations (Quality and IT) for over 20 years.

Eduardo Sanchez, BS, MS – Currently, Mr. Sanchez manages R&D projects and workforce development programs at Northeastern University's Burlington Innovation Campus, focusing on biomanufacturing, quality control, analytical characterization, and GxP standards. He is dedicated to bridging research, industry, technology, and education to drive innovation in life sciences. Mr. Sanchez is a passionate lifelong learner of science and an enthusiastic advocate for emerging technologies. With over a decade of experience in the life sciences, he has collaborated with partners across government, academia, and industry to drive innovation and impact. Mr. Sanchez's career began at the Centers for Disease Control and Prevention (CDC) in Atlanta as a Research Chemist and ORISE Fellow. During the pandemic, he was one of Northeastern University's core team members tasked with establishing the Life Sciences Testing Center (LSTC), the university's COVID-19 testing lab.

Brian Stamper, BS, MS – Mr. Stamper is an Executive Director in Cell Therapy Operations at AstraZeneca, overseeing the company's new Cell Therapy manufacturing facility in Rockville, Maryland. With 25 years of industry experience, he has held roles in Process Development and Operations at AstraZeneca, Eli Lilly, and Kite Pharma. Mr. Stamper also dedicates his time to advancing workforce development for life sciences through his volunteer work with the Maryland Tech Council BioHub program and the Maryland Governor's Workforce Development Board.

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Agenda

Continuing Education

This conference qualifies for 16.0 hours of continuing education credit.

Monday, August 11, 2025
Morning Session: Moderator – Lynne Ensor, PhD

8:00 – 9:00	Registration*	
9:00 – 9:10	Welcome*	Lynne Ensor, PhD
9:10 – 9:45	**Dashboards, Databases, and Disclosure: FDA's Radical Transparency**	Sarah Barkow, PhD
9:45 – 10:15	**Technology/Innovation (Inspection Tools) – Industry Perspective**	Ranjith Ramakrishnan
10:15 – 10:35	Break*	
10:35 – 11:05	**FDA Changes and Industry Impact**	Deb Autor
11:05 – 11:35	**Properly Preparing for an FDA Inspection**	Maya Davis, PhD
11:35 – 12:05	**Center Update: CDER**	Michael Davis, MD, PhD, FDA, CDER
12:05 – 12:30	**Question and Answer Session**	Morning Speakers
12:30 – 1:45	Lunch*	

Afternoon Workshops

1:45 – 3:15

Workshop 1: Planning a Virtual Audit Using Innovative Technology (Inspection Tools)

Eduardo Sanchez
Tamika Cathey

- Introduction: Bill and Melinda Gates Foundation and HaloLens2 and Northeastern University
- Historical Context: Virtual Technologies like HaloLens2 and why it was created
- Pro and Cons: Lessons learned and unique challenges. Anchor: White Paper Collaboration with WHO, Northeastern, Peter Baker, and former FDA expert Ms. Cathey along with user knowledge thus far. **Click here to read the White Paper**
- The Future: Emerging Technologies Discussion and Regulatory Feedback (use of virtual tools and FDA guidance on RRAs 2022/2023)
- Plug and Play Session: Guest Interaction using HaloLens 2- How to inspect for proper donning and doffing of gloves using a Microsoft HoloLens AR Headset & remote auditor engagement exercise

Workshop 2: How Do You Prepare for FDA Remote Regulatory Assessments?

Ileana Barreto-Pettit
Maya Davis, PhD

This workshop will introduce remote regulatory assessments (RRAs) including the two main types of RRAs (surveillance and pre-approval), FDA's regulatory authority, relevant forms, guidance documents, and types of information requested. The interactive portion of this workshop will explore case studies, discuss regulatory actions, explore challenges, and discuss how to remain prepared for RRAs.

Workshop 3: Communicating with Regulatory Authorities: Responding to Inspection Observations and Avoiding Enforcement Actions

Jennifer Bragg
Ted Lis
Julia Marré, PhD
Jennifer Kang

Attendees will learn how to evaluate inspection findings and effectively communicate remediation activities to regulatory authorities. Attendees will also learn how to challenge FDA when firms believe the regulatory findings are not justified.

Agenda

Continuing Education

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	Workshop 4: Contamination Control in Drug Substance and Drug Product Manufacturing This workshop provides a comprehensive overview of preventing chemical and microbiological contamination in pharmaceutical drug substances and drug products, a critical aspect of Good Manufacturing Practices (GMP). The session will delve into the regulatory landscape, effective control strategies, and real-world examples of non-compliance.	Chris Middendorf Robert Darius
3:15 – 3:35	Break*	
3:35 – 5:05	**Workshops Session 2 - the above workshops will be repeated**	
5:30 – 7:00	Networking Reception*	

Tuesday, August 12, 2025
Morning Session: Moderator – John Hyde

8:30 – 8:35	Announcements*	
8:35 – 9:10	**Regulatory Updates: Where Is AI (Artificial Intelligence) Going?**	Tala Fakhouri, PhD, MPH
9:10 – 9:50	**Current Trends on How AI and Other Virtual Technologies are Being Used for Quality Activities to Support Drug Manufacturing**	Jeff W. Orlov Tammy Hanley
9:50 – 10:10	Break*	
10:10 – 10:40	**Digitalization in Pharmaceutical Manufacturing Development & Quality Oversight**	Christine Moore, PhD
10:40 – 11:10	**In-Depth Look at a Phased Crisis Management and Recovery Action Plan to Support Supply Chain Resiliency**	Tim Marini
11:10 – 11:40	**Advancing Microbial Control: Recent Standards and Rapid Methods for Modern GMP**	Brett Howard, PhD, JD
11:40 – 12:10	**Question and Answer Session**	Morning Speakers
12:10 – 1:25	Lunch*	

Afternoon Workshops

1:25 – 2:55	**Workshop 1: The Road to AI: "Why" and "How" Data Governance Should Pave the Way** Artificial Intelligence/Machine Learning (AI/ML) technologies are revolutionizing the biopharmaceutical industry with limitless promise to enhance and innovate effective medicines for patients from all over the world. Amidst the buzz and promise, assuring the quality and integrity of data is not only a strategic imperative but fundamental to established and emerging Health Authority regulations and guidance. Further, basic data quality and data integrity issues continue to impact organizations; not only disrupting the digital ecosystems fueling AI/ML but potentially impacting the quality of medicines and placing patients at risk. Join us for an interactive workshop tackling strategic data governance and the "road" to AI. Participants will explore the evolving regulatory landscape and industry-recognized best practice for data governance and AI/ML technologies, and then breakout with colleagues to "build" a roadmap to pave the way to AI with reliable data!	Kir Henrici Charles Gibbons

Agenda

Continuing Education

This conference qualifies for 16.0 hours of continuing education credit.

Workshop 2: Quality and Regulatory Challenges of Sustainability Initiatives in Pharmaceutical Manufacturing Facilities

John Hyde
Brian Stamper

While pharmaceutical manufacturing is a critical industry that plays a vital role in public health by producing life-saving medications and treatments, the industry is also associated with significant environmental challenges, including high energy consumption, water usage, and waste generation. In recent years, growing awareness of environmental issues and increasing regulatory pressures have led pharmaceutical companies to adopt sustainability initiatives aimed at minimizing their environmental impact while maintaining efficiency and compliance with regulatory standards. These sustainability initiatives have posed quality and regulatory challenges, and this interactive workshop will address these in the energy consumption, water usage, and waste generation.

Workshop 3: AI Tools – Supporting Document Writing – Case Studies

David Jaenisch
Tamika Cathey

- How to use AI
- Deviations, KPIs (Key Performance Indicators), Technical (Process Validation)
- Before Human Interaction and After
- Pros and Cons
- Human Review

Workshop 4: Future of Evolving Regulatory Oversight

Sarah Barkow, PhD
Brooke Higgins

This interactive workshop explores the future of evolving regulatory oversight, covering current trends, future predictions, and potential scenarios. Through engaging discussions and case studies on evolving oversight tools, compliance and reliance pilots (e.g. HC, TGA, MHRA single inspection pilot), and changes to FDA/global HA inspections, participants will gain insights into the shifting landscape of regulatory practices and their implication across various sectors.

2:55 – 3:15 Break*

3:15 – 4:45 **Workshops Session 2 - the above workshops will be repeated**

6:00 – 8:00 **Evening Social***

An informal gathering for drinks and dinner. Included in the price of your registration fee. Dress casual.

Agenda

Continuing Education

This conference qualifies for 16.0 hours of continuing education credit.

Wednesday, August 13, 2025
Morning Session: Moderator – Robert Darius

8:30 – 9:10	**Update on FDA's QMM (Quality Management Maturity) Initiative: Industry Perspective**	Maya Davis, PhD
9:10 – 9:45	**Industry Pilot Case Study**	Maria Amaya, PhD
9:45 – 10:20	**Quality Culture and Emerging from Regulatory Setbacks/Challenges**	Barry Cook
10:20 – 10:40	Break *	
10:40 – 11:10	**No Barriers to Success: Modern Technology in Sterile Filling Operations**	Erika Pfeiler, PhD
11:10 – 11:50	**An Inspectional Perspective**	Alonza Cruse
11:50 – 12:20	**Surfing the Latest Waves: CDER Compliance Updates from a Former Regulator**	Brooke Higgins
12:20 – 12:50	**Ask Former Regulators Q&A Panel**	Alonza Cruse Maya Davis, PhD Erika Pfeiler, PhD Ileana Barreto-Pettit Brooke Higgins
12:50	Closing*	

*Denotes non-educational activity

Registration

29TH ANNUAL
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Fees

	Industry	U.S. Gov't & Press
EARLY DISCOUNT: Payment Received By May 30, 2025	❑ $3195	❑ $1995
Payment Received After May 30, 2025	❑ $3395	❑ $1995

Includes conference materials, continental breakfasts, breaks, lunches, networking reception, evening social per agenda.

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Hotel

Hyatt Regency Chesapeake Bay Hotel
100 Heron Blvd, Cambridge, MD 21613 | (410) 901-1234
$259 single/double

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