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August 17 – 19, 2026 | Cambridge, Maryland
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About the Conference

The 30th Annual GMP by the Sea Conference, taking place August 17–19, 2026, at the Hyatt Regency Chesapeake Bay in Cambridge, Maryland, is a premier forum for pharmaceutical and biotechnology professionals focused on Good Manufacturing Practice (GMP) compliance, regulatory intelligence, and quality innovation. Hosted by Pharma Conference Inc, this milestone event brings together regulators, industry leaders, and subject matter experts to explore the evolving landscape of global regulatory oversight and manufacturing excellence.

Marking its 30th year, GMP by the Sea continues its tradition of delivering timely, practical insights into the most pressing challenges facing the life sciences industry. The 2026 program reflects a period of significant transformation, with regulators such as the FDA advancing toward a more data-driven, "always-on" compliance model. Attendees will gain critical perspective on new regulatory initiatives, inspection trends, and policy shifts shaping both domestic and international GMP expectations.

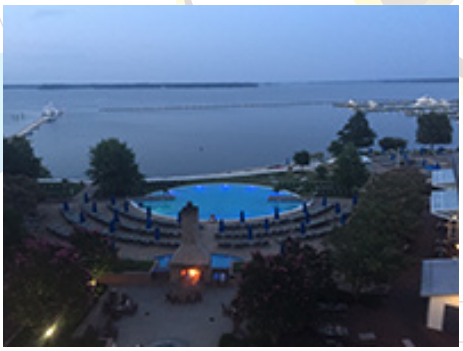
The conference opens with a keynote address from invited Robert F. Kennedy Jr., Secretary of the U.S. Department of Health and Human Services, followed by sessions examining the changing scope of FDA oversight, including emerging inspection strategies, global regulatory alignment, and initiatives such as FDA Pre-Check, commissioner's national priority voucher program, and unannounced inspections. International perspectives from invited agencies including Health Canada and the MHRA further broaden the discussion on global compliance expectations.

A central theme of this year's conference is the integration of artificial intelligence and digital technologies into quality and regulatory systems. Dedicated sessions will explore FDA's evolving position on AI, as well as its application in supplier risk management, predictive quality, data integrity, and inspection readiness. Through expert presentations and a multi-speaker fireside chat, participants will gain both strategic and practical guidance on leveraging AI responsibly while maintaining compliance.

Interactive workshops are a cornerstone of the GMP by the Sea experience, offering attendees the opportunity to engage deeply with real-world challenges. Topics include inspection readiness and audit management, FDA enforcement response strategies, manufacturing outsourcing, data integrity in an AI-enabled environment, and effective investigation practices. These sessions emphasize hands-on learning, peer exchange, and actionable tools that can be immediately applied within organizations.

The final day of the conference focuses on quality culture, advanced manufacturing technologies, outsourcing decisions, and balancing accelerated regulatory pathways with scientific rigor. A closing panel featuring former regulators provides attendees with candid insights into enforcement expectations and practical strategies for maintaining a state of control in an increasingly complex environment.

In addition to its robust educational program, GMP by the Sea offers valuable networking opportunities, including a welcome/networking reception and evening social, fostering collaboration across industry, regulatory, and consulting communities.



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 foreign regulators (invited), FDA (invited), former 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:

"Very well organized event with a good range of topics – really liked the AI information. Workshops were excellent, and I appreciated the talk time (~30 minutes) as easy to concentrate."

"I had an amazing experience at GMP By The Sea. The subject content is very educational and informative. The hosts were great, and registration team was amazing. All speakers were very knowledgeable on the subject at hand and delivery was very engaging."

"It was great hearing from those who used to work at the FDA. Very good insights."

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

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/events/en-US/group-booking/CHESA/G-GPBS

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About the Speakers

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.

Roy T. Cherris, BSc – With over 45 years of Quality Assurance experience, Mr. Cherris is a founder and Senior Advisor of Bridge Associates International Consultancy. He is also CSO and founder of InQuest Science, providing expert digital systems for visual inspection MVI/AVI data management. Mr. Cherris has an extensive background in forensic microscopy, and he co-authored *Visual Inspection and Particulate Control 2016*, PDA bookstore. He has been active in PDA leading the task force for "Difficult to Inspect Parenteral" products Technical Report TR-79. Mr. Cherris remains an active member of the USP Expert Panel for Visual Inspection of parenterals.

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. He first joined ORA in 1983 as a microbiologist. Mr. Cruse received his Bachelor of Science degree in Medical Technology from York College (City University of New York).

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.

Vid Desai, BSc – A nationally recognized healthcare technology leader with 35+ years of experience across regulatory agencies, pharmaceutical companies, and medical device firms, Mr. Desai is CEO of Desai Technology Consulting LLC. Prior to founding Desai Technology Consulting, he served as Chief Information Officer at the US FDA, where he led a $1 billion digital portfolio and founded the Office of Digital Transformation — the first CIO to serve on the agency's Executive Committee. Mr. Desai's career spans senior roles at Vyaire Medical, IQVIA, and GlaxoSmithKline. A Forbes CIO Next and FedHealthIT Lifetime Achievement Award recipient, he holds a first-class Computer Science degree from the University of London.

David Doleski, BS – Mr. Doleski is the Compliance Head, Vaccines for Sanofi and is responsible for ensuring inspection readiness and regulatory compliance. He was the Head of Global Quality Audit in Sanofi. Previously, Mr. Doleski served in FDA for over 27 years in leadership positions related to inspection and review programs for drugs and biologics. His last FDA position was Acting Deputy Director for OPF (now OPMA), an office responsible for pre-approval inspections and application reviews.

Lynne Ensor, PhD – Dr. Ensor is President, Ensor Pharma Biotech Consulting, LLC, where she provides strategic regulatory consulting to the pharmaceutical and biotechnology sectors. She is a seasoned expert in sterile product manufacturing, regulatory affairs, compliance, and remediation. Dr. Ensor's previous consulting experience includes serving as Senior Vice President and the Head of Global Compliance Consulting at Parexel International, as well as Senior Global Managing Director for Pharma Biotech Consulting and Life Sciences Training at NSF International. Prior to consulting, she served for 21 years at the U.S. Food and Drug Administration (FDA) in the Center for Drug Evaluation and Research (CDER). Dr. Ensor 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. She was a member of the 2020-2025 U.S. Pharmacopeia's Microbiology Expert Committee. Dr. Ensor's prior experience also includes Roche Biomedical Laboratories, script consulting for the Discovery Channel, and the University of Maryland's School of Medicine. She earned a BS in Biology and a PhD in Microbiology from the University of Maryland.

About the Speakers

Chris Fanelli, JD – Mr. Fanelli is Partner, FDA Compliance, with Sidley Austin LLP. A former FDA enforcement lawyer with more than a decade of experience counseling life sciences companies on sensitive compliance and regulatory matters, his practice sits at the intersection of FDA regulatory and FDA compliance. In addition to leading internal investigations into sensitive manufacturing compliance matters, managing critical FDA inspectional matters, and counseling on a variety of GxP compliance matters, he also routinely counsels clients on critical regulatory matters. This includes developing and implementing strategies to address Complete Response Letters, responding to Information Requests, and strategic FDA engagement.

Mary Howe, BS, MS – Ms. Howe is Director, Governance Predictive Insights Integrator at Bristol Myers Squibb, with more than 20 years of experience in quality management, regulatory compliance, and data driven performance improvement. She serves as the global process owner for Management Review, connecting leaders to actionable data and process analytics. Ms. Howe leads enterprise initiatives in predictive analytics, harmonized processes, and quality management maturity, and advances industry thinking externally. An award winning change agent, she mentors teams and drives innovation across the enterprise. Ms. Howe holds an advanced degree in Microbiology and Molecular Genetics from Rutgers University.

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 a generative AI consultant with Prompting Integration and Consulting LLC from San Diego. He has 15 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.

Alison Laughlin, BA – Ms. Laughlin is a quality and sterility assurance leader with more than 25 years of experience across the pharmaceutical, biopharmaceutical, biologics, and medical device industries. As Associate Director, HPS Strategic Network Quality & Compliance at Boehringer Ingelheim, she provides global expertise in microbiology, aseptic processing, GMP assessments, and regulatory inspection support. Throughout her career, Ms. Laughlin has led complex investigations, strengthened contamination control programs, and advanced quality systems to enhance performance and quality culture across global manufacturing networks.

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 was convenor for the working group revising ISO 14644-5, Cleanrooms and Associated Controlled Environments — Part 5: Operations, which was published in May 2025. He is chairman-elect of ISO Technical Committee 209, Cleanrooms and Associated Controlled Environments.

Niraj Mehta, PhD – Dr. Mehta is the Senior Vice President of Quality Compliance and Sustainability at Lupin Pharmaceuticals Inc, a generic drug company. The Quality Compliance Organization at Lupin oversees activities such as GMP training, auditing, investigations, permanent inspection readiness, regulatory intelligence and governance of Quality Council, Recalls, Field Alert Reports, Complaints etc. He is formerly the Executive Director/Global Quality Lead for Strategic Programs and Regulatory Intelligence team within Merck's Manufacturing Division (MMD) where he was responsible for the management of external policy, and execution of processes and programs to ensure MMD's Quality Compliance excellence including enabling a Quality Management Maturity program within MMD. Prior to joining Merck, Dr. Mehta spent over 10 years at the U.S. FDA in various roles within CDER and the Commissioner's Office where he facilitated the adoption and implementation of the US-EU MRA. He has a Ph.D. in Pharmacology and Molecular Sciences from the Johns Hopkins School of Medicine.

Christopher T. Middendorf, BS, MS – Mr. Middendorf brings more than 20 years of FDA experience to his work in global pharmaceutical compliance. During his FDA career, he conducted inspections around the world and spent three and a half years stationed in FDA's Beijing Office. His final role at the agency was Senior Policy Advisor in CDER's Office of Compliance. After leaving 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 assessing quality management maturity. He later served as Vice President, Technical, Strategic Compliance at Parexel, concentrating on advancing BLAs to approval and correcting negative PLI outcomes in aseptic manufacturing. He returned to Hogan Lovells in 2024, where he continues to guide clients through FDA enforcement challenges and expand the strategic use of Quality Management Maturity (QMM) as a driver of operational efficiency and business performance.

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About the Speakers

Jahanvi Miller, BS, MBA – Ms. Miller is CEO & Founder of JahvanMed Advisors LLC. She has spent over 25 years in Life Sciences shaping quality organizations in large pharmaceutical and device companies such as Johnson & Johnson, Amgen, Otsuka, and Baxter. Ms. Miller's experience integrates quality-centric approaches which enable operational excellence. She also engages with internal and external stakeholders to meet and implement global regulatory expectations throughout the product life cycle and frameworks to meet industry standards (such as ISO 9001 and GMPs) to ensure product safety and regulatory compliance (including early warning signals for proactive compliance and effective quality systems). Ms. Miller has a deep understanding of regulatory requirements, technology and innovation, in addition to business sustainability.

Scott Nichols, PhD – Dr. Nichols graduated from the University of Iowa with a BS in Biochemistry, continued as a Fulbright Scholar in Microbiology at the Pasteur Institute, and completed his PhD at Johns Hopkins in Molecular Biophysics. He worked as a microbial control and sterility assurance lead reviewer and lead inspector at the FDA for CDER-regulated BLAs, and as a consultant for regulatory and compliance issues for biotechnology and cell therapy clients. Dr. Nichols is now Senior Director of Quality for Kite Pharma, a leading CAR-T manufacturing company with facilities in the US and EU and worldwide product distribution of autologous cell therapy products.

Michelle Ritchea-Freedman, BA, MS – As Business Process Owner for Audit and Self-Inspection at Sanofi, Ms. Ritchea-Freedman is accountable for the design, evolution, and implementation of global Quality Audit and Self-Inspection standards across R&D, industrial, and commercial entities. She brings over 20 years of pharmaceutical industry experience and holds a Master's in Regulatory Affairs from Northeastern University and a Bachelor's in Chemistry from the University of Massachusetts Amherst.

Michael C. Rogers, MS – Mr. Rogers is a seasoned public health and regulatory leader whose 34 year career with the US Food and Drug Administration spans domestic and international inspections, executive leadership, and global program oversight. He began his career as a field investigator conducting domestic and foreign inspections across multiple program areas, building a foundation of operational and scientific rigor that shaped his leadership approach. He retired as a member of FDA's Executive Leadership Team serving as the Associate Commissioner for Inspections and Investigations, overseeing the largest cross-programmatic inspectorate in the world. Mr. Rogers also has extensive international experience. As a former U.S. Diplomat, he served as the FDA's Regional Director for Latin America, living in Costa Rica and managing FDA offices in Costa Rica, Mexico, and Chile. Mr. Rogers' portfolio covered 44 countries and territories, where he developed international agreements, strengthened regulatory partnerships, and advanced FDA's global presence. Today, Mr. Rogers is a Principal at Canal Row Advisors, a consulting firm serving life sciences companies. He works with organizations to strengthen operations, elevate quality systems, and maintain regulatory standing—drawing on decades of experience leading global inspection programs and shaping FDA's modern regulatory landscape.

Sebastian Scheler, MSc – Mr. Scheler is the Co-Founder/Managing Director of Innerspace GMBH. He is passionate about driving innovation through his company's Frame-by-Frame Technology – an automated solution for process modelling, risk assessment and knowledge management, which empowers organizations to automate and design processes, streamline operations, improve scalability, and mitigate risks in life science manufacturing processes. In his role as Managing Director at Innerspace, Mr. Scheler oversees the continuous development and optimization of this ground breaking approach.

David Schneider, PhD – Dr. Schneider is the Founder and CEO of Qualifyze. He holds a PhD in Information Systems and previously worked as a consultant at McKinsey & Company. Qualifyze offers proactive, AI-enabled supplier risk management solutions for the life sciences industry, supporting hundreds of clients worldwide, including most of the global top 100 pharma. The platform leverages insights from validated data sources such as supplier audits, regulatory data, and proprietary customer data to strengthen quality, compliance, and resilience across global supply chains.

Douglas Stearn, JD – Mr. Stearn is a consultant with Canal Row Advisors. He served for more than 17 years in senior managerial roles at the FDA, leading regulatory, compliance, enforcement, and policy activities across a broad range of products. Mr. Stearn most recently served in FDA as the principal deputy associate commissioner for inspections and investigations, providing advice and leadership to ensure the successful execution of all programs while directly overseeing emergency operations, investigator training, and operational policy. Prior to this, he led regulatory and compliance efforts across FDA's food safety program — including overseeing outbreak response, compliance, food safety policy, and dietary supplement regulation — as a deputy center director in the Center for Food Safety and Applied Nutrition (CFSAN). Mr. Stearn's earlier FDA career included roles as director of the Office of Enforcement and Import Operations in the Office of Regulatory Affairs and as a deputy director in the Office of Compliance in the Center for Drug Evaluation and Research (CDER). He previously served for 15 years as a trial attorney in the U.S. Department of Justice's Office of Consumer Litigation where he litigated numerous food and drug cases.

Brian Trdina, BS, MS – Mr. Trdina is the Director of Emerging Technology for AstraZeneca's Global Quality Audit Team, a position he has held since 2024. He has been with AstraZeneca since 2018, acting as the GQA Regulatory Inspection and Surveillance Director and the Associate Director, Biologics - World-Wide Audit Group between 2018 and 2024. Prior to joining AstraZeneca, Mr. Trdina held positions with Wyeth, Sanofi-Aventis, and MedImmune.

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Agenda

Continuing Education

This conference qualifies for 16.0 hours of continuing education credit.

Monday, August 17, 2026

Morning Session: Moderator – Lynne Ensor, PhD, former FDA

8:00 – 9:00	Registration*	
9:00 – 9:10	Welcome*	Lynne Ensor, PhD, former FDA
9:10 – 9:55	**Keynote Address**	Robert F. Kennedy, Jr, HHS – invited
9:55 – 10:30	**The Changing Landscape of FDA's Regulatory Oversight**	Michael Rogers, former FDA
10:30 – 10:50	Break*	
10:50 – 11:25	**FDA Initiatives Around Inspections:** • **FDA Precheck** • **Commissioner's National Priority Vouchers** • **Unannounced Foreign Inspections** • **On-shoring manufacturing**	To Be Determined
11:25 – 12:10	**Foreign Regulatory Updates: Initiatives Around Inspections and GMP Facilities**	Health Canada - invited EMA - invited MHRA - invited
12:10 – 1:00	**Question and Answer Session**	Morning Speakers Plus: Alonza Cruse, former FDA
1:00 – 2:15	Lunch*	

Afternoon Session: Workshops

2:15 – 3:45	**Workshop 1: Managing Inspection Readiness for GMP: Ensuring Currency with Enforcement Trends and Emerging Risks** This workshop equips GMP leaders to sustain inspection readiness by translating current enforcement trends into practical actions. <u>Objectives include:</u> • Identifying emerging risks across manufacturing and quality systems • Approaches for training and targeted coaching to support successful inspection outcomes. • Establishing a value-added practice like soft skills – conflict management, time management (in correlating to inspection audit) • Emerging FDA inspectional measures for streamlining their process (Finalized guidance on Remote Regulatory Assessment (RRAs), ELSA and Agentic AI, Advance analytics etc.)	Tamika Cathey, former FDA Brian Trdina

Agenda

Continuing Education

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Workshop 2: FDA Current Initiatives (or Awareness)

Alonza Cruse, former FDA
Douglas Stearn, JD, former FDA

As we move through 2026, the FDA is undergoing its most significant operational transformation in a decade. Driven by the 2025 "Regulatory Relief" Executive Orders and recent 2026 legislative reauthorizations, the Agency has shifted from a reactive oversight model to a data-driven, "always-on" compliance posture. This session will touch on topics such as the launch of FDA Pre-check, National Priority review program and unannounced inspections.

Workshop 3: Use of Recorded Video in a GMP Environment

Ted Lis, JD
Sebastian Scheler

- Legal Aspects to be Discussed
- Case Study - AI Analysis of Aseptic Behavior

Workshop 4: Design and Management of an Audit Program

David Doleski, former FDA
Michelle Ritchea-Freedman

This session will explore best practices related to the design and management of corporate audit programs. The goal of an audit program should be to proactively identify compliance issues before they become inspection issues. Discussions will include composition of the audit team, use of automation or AI as audit tools, use of data driven signals or metrics, risk-based approach for audit agendas, and factoring other audits, self-inspections or inspections into the agenda.

3:45 – 4:05	Break*	
4:05 – 5:35	Workshops Session 2 - the above workshops will be repeated	
6:00 – 7:30	**Networking Reception***	

Tuesday, August 18, 2026

Morning Session: Moderator – Niraj Mehta, PhD, former FDA

8:30 – 8:35	Announcements*	
8:35 – 9:10	**FDA Update – AI Initiatives** • Implementation • Position on AI	FDA invited
9:10 – 9:40	**AI-Powered Supplier Site Risk Management: From Compliance to Resilience**	David Schneider, PhD
9:40 – 10:00	Break*	

Agenda

Continuing Education

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10:00 – 10:30	**Digitalization of Visual Inspection Data and Lifecycle Management**	Roy Cherris
10:30 – 11:00	**Driving Predictive Quality – From Evolution to Impact**	Mary Howe
11:00 – 11:30	**The Changing Regulatory Landscape – How Will It Impact You?**	Vid Desai, former FDA
11:30 – 12:15	**Fireside Chat**	Moderator: Maya Davis, PhD, former FDA Morning Speakers and AI Workshop Leader- David Jaenisch
12:15 – 1:30	Lunch*	

Afternoon Session: Workshops

1:30 – 3:00	**Workshop 1: Navigating Manufacturing Outsourcing** • Tools • Quality Agreements • Managing Quality Challenges • Case Study – How to Optimize Interactions	John Hyde Ted Lis, JD To Be Determined
	Workshop 2: Navigating FDA Enforcement: How to Respond When You Receive a 483 or Warning Letter Learn how to effectively respond when FDA issues a Form 483 or Warning Letter. This session outlines the essential steps, timelines, and strategic considerations required to address FDA's concerns, restore a state of control, reinforce quality system performance, and demonstrate long term, sustainable compliance to regulators.	Chris Middendorf, former FDA
	Workshop 3: Data Integrity and Using AI Tools: Performing Compliance Investigations with and against AI • Introduction of AI tools/Determine and improve your AI knowledge level • Differences between skilled AI implementation and potentially dangerous novice usage • ALCOA principles and how to integrate them into AI to stay compliant with data integrity • How to handle potentially dangerous AI interactions and human review • AI organization policies in compliance • Final: Simulation of root cause analysis run by AI compared live against a human expert	David Jaenisch Tamika Cathey, former FDA

Agenda

Continuing Education

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	Workshop 4: Handling Quality Challenges through Effective Investigations This workshop will explore practical strategies for handling quality challenges through effective root cause analysis and CAPA development. This interactive session uses real-world scenarios, group discussion, and problem-solving exercises to strengthen investigation skills and drive sustainable quality improvements across operations.	Alison Laughlin
3:00 – 3:20	Break*	
3:20 – 4:50	**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 and cool.	

Wednesday, August 19, 2026

Morning Session: Moderator – Alonza Cruse, former FDA

8:30 – 9:05	**Quality Culture Under Pressure: Why FDA Inspections Expose Culture Before Systems**	Jahanvi Miller
9:05 – 9:40	**To Outsource or not to Outsource: Understanding the Benefits and Risks of CDMOs** • Sponsor vs. CDMO/CRO accountability • Quality agreements that fail in practice • Oversight models FDA expects	Chris Fanelli, JD, former FDA
9:40 – 10:15	**Technology Applications and Advanced Manufacturing**	To Be Determined
10:15 – 10:35	Break*	
10:35 – 11:05	**Recent Regulatory Inspection and Compliance Trends**	Maya Davis, PhD, former FDA
11:05 – 11:35	**Regulatory Quality Initiatives and Manufacturing Flexibility**	Scott Nichols, PhD, former FDA
11:35 – 12:05	**The Challenges in FDA's Inspectional Capacity in Meeting the Expectations Placed Upon the Agency**	Douglas Stearn, JD, former FDA
12:05 – 12:45	**Ask Former Regulators Q&A Panel**	Michael Rogers, Douglas Stearn, JD, Maya Davis, PhD , Niraj Mehta, PhD, Scott Nichols, PhD
12:45	Closing*	

Registration

30TH ANNUAL GMP BY THE SEA

Fees

	Industry	U.S. Gov't & Press
EARLY DISCOUNT: Payment Received By May 29, 2026	❑ $3195	❑ $1995
Payment Received After May 29, 2026	❑ $3395	❑ $1995

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

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* To receive the group discount, attendees must register concurrently and all pay at the same time.

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Payment

- All credit card transactions are processed in US Dollars (your bank will convert to your local exchange rate when billing)
- You will receive a confirmation via email as soon as the registration is processed. In order to receive the early registration price, payment must be made by the deadline specified in the brochure. (Taxpayer ID #27-1438344)
- Registrations must be accompanied by full payment.

Payment Terms: Conference attendees must be paid in full prior to conference start date.

Hotel

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

A limited number of rooms have been blocked at the special rate listed per night. Rate is available 3 nights either side of the conference dates, based upon availability of rooms. **Hotel reservations must be made on or before July 31, 2026, in order to guarantee the special rate.** Individuals are responsible for making their own hotel reservations. **If calling, you must mention the title of the program AND Pharma Conference when making your reservation in order to obtain these special rates. Please do not use travel agents for reservations.**

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For additional information, contact Pharma Conference Inc: (830) 315-0055 • e-mail: contactus@pharmaconference.com

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