The top GMP conference in the U.S.!

30TH ANNUAL

GMP BY THE SEA

GMP BY THE SEA 30TH ANNIVERSARY

August 17 – 19, 2026 | Cambridge, Maryland
Hyatt Regency Chesapeake Bay Hotel

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About the Conference

The 30th Annual GMP by the Sea Conference (August 17–19, 2026) convenes pharmaceutical and biotechnology professionals for three days of focused discussion on Good Manufacturing Practice (GMP) compliance, FDA expectations, and emerging technologies shaping regulated manufacturing. Held at the Hyatt Regency Chesapeake Bay in Cambridge, Maryland, this milestone event brings together regulators, industry leaders, and quality professionals to address today's most pressing compliance and operational challenges.

A central strength of GMP by the Sea is its robust FDA participation. Senior leaders and subject matter experts from across FDA are expected to provide center and compliance updates, inspectional insights, and forward looking perspectives. **Invited** regulatory speakers include Keynote speaker Robert F. Kennedy, Jr. (U.S. Department of Health and Human Services); FDA's OII, CDER and CBER Directors, among other FDA personnel.

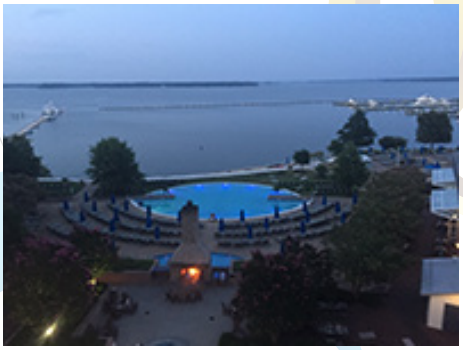
The 2026 program emphasizes FDA and industry alignment in an era of rapid technological change, with multiple sessions examining artificial intelligence, data integrity, and advanced analytics in GMP environments. Highlights include FDA perspectives on AI initiatives and implementation, the future of visual inspection and automated rejection analysis, predictive quality models, and the application of ALCOA principles in an AI enabled regulatory landscape.

In addition to innovation, the conference addresses core GMP risks and realities, including inspection readiness, audit management, quality culture, outsourcing oversight, supplier qualification, and effective responses to FDA Form 483s and Warning Letters. These themes are reinforced through a comprehensive workshop program that allows attendees to select and repeat sessions on inspection readiness, data integrity, audit oversight, manufacturing outsourcing, CAPA effectiveness, and managing quality challenges.

The conference concludes with FDA Center compliance updates, inspectional initiatives, and an "Ask the FDA" Q&A, offering attendees a rare opportunity for open dialogue with regulators. Networking receptions and social events throughout the program further support peer exchange and relationship building.

For professionals responsible for quality, manufacturing, compliance, and regulatory oversight, the 30th Annual GMP by the Sea Conference delivers practical insight, regulatory clarity, and forward looking discussion in a collaborative, highly regarded forum.

We look forward to welcoming you to this highly informative and worthwhile event.



Register online at www.pharmaconference.com

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 (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."

"I enjoy the program every year. The content is very useful. I enjoy the Center Updates especially with the ever-changing climate we are currently in."

About the Speakers

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.

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.

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

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.

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.

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.

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.

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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

8:00 – 9:00	Registration*	
9:00 – 9:10	Welcome*	Lynne Ensor, PhD
9:10 – 9:55	**Keynote Address**	Robert F. Kennedy, Jr, HHS – invited
9:55 – 10:25	**Center Update: OII**	FDA invited
10:25 – 10:45	Break*	
10:45 – 11:15	**Center Update: CBER**	FDA invited
11:15 – 11:45	**Center Update: CDER**	FDA invited
11:45 – 12:15	**Question and Answer Session**	FDA invited
12:15 – 1:30	Lunch*	

Afternoon Session: Workshops

1:30 – 3:00	**Workshop 1: Inspection Readiness** • Soft skills – conflict management, time management (in correlating to inspection audit) • Inspection tools	Tamika Cathey Sarah Barkow, PhD
	Workshop 2: FDA Current Initiatives (or Awareness) 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.	Alonza Cruse FDA invited FDA invited
	Workshop 3: Use of Recorded Video in a GMP Environment • Legal Aspects to be Discussed • Case Study - AI Analysis of Aseptic Behavior	 Ted Lis To Be Determined
	Workshop 4: Audit Management • Outsourcing Audit oversight • Risk-based approaches and tools	David Doleski Michelle Ritchea-Freedman

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3:00 – 3:20	Break*	
3:20 – 4:50	Workshops Session 2 - the above workshops will be repeated	
5:30 – 7:00	**Networking Reception***	

Tuesday, August 18, 2026

Morning Session: Moderator – To Be Determined

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*	
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	**What Does ALCOA Mean for an AI World** • Data Governance/Integrity Maintenance	FDA invited
11:30 – 12:15	**Fireside Chat**	Moderator: Maya Davis, PhD 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**	FDA invited
	• Tools	John Hyde
	• Quality Agreements	Ted Lis
	• Managing Quality Challenges	To Be Determined
	• Case Study – How to Optimize Interactions	

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Continuing Education

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	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
	Workshop 3: Data Integrity and Using AI Tools: Performing Compliance Investigations with and against AI • Simulation of root cause analysis run by AI compared live against a human expert • Differences between skilled AI implementation and potentially dangerous novice usage • Determine and improve your AI knowledge level • AI organization policies in compliance • How to handle potentially dangerous AI interactions and human review	David Jaenisch Tamika Cathey Maya Davis, PhD
	Workshop 4: Handling Quality Challenges • Determining Root Cause for deviations, investigations, product complaints • CAPAs	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.	

Agenda

Continuing Education

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Wednesday, August 19, 2026

Morning Session: Moderator – To Be Determined

8:00 – 8:30	**CDER Progress to Date Under the New Administration**	FDA invited
8:30 – 9:05	**Quality Culture Under Pressure: Why FDA Inspections Expose Culture Before Systems**	FDA invited
9:05 – 9:40	**The Hidden Risk in Outsourcing: Oversight, Accountability, and Control** • Sponsor vs. CDMO/CRO accountability • Quality agreements that fail in practice • Oversight models FDA expects • Managing risk without micromanaging	FDA invited
9:40 – 10:15	**Current FDA Inspection Practices for Pharmaceuticals and Biologics**	FDA invited
10:15 – 10:35	Break*	
10:35 – 11:05	**OII's Inspectional Initiatives**	FDA invited
11:05 – 11:35	**CBER Compliance Update**	FDA invited
11:35 – 12:05	**CDER Compliance Update**	FDA invited
12:05 – 12:45	**Ask FDA Q&A Session**	FDA invited
12:45	Closing*	

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

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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Register 10 or more attendees from the same company and receive 15% off the registration price!*

* 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.**

Reservations:
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