The top GMP conference in the U.S.!

29TH ANNUAL

GMP BY THE SEA

AUGUST 11 – 13, 2025 | CAMBRIDGE, MARYLAND

Hyatt Regency Chesapeake Bay Hotel

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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 updates and current initiatives to be shared by invited United States Food and Drug Administration (FDA) Center directors and leadership, including Dr. Peter Marks (CBER), Michael Rogers (Office of Inspections and Investigations) and the new acting CDER director (Dr. Jacqueline Corrigan-Curay).

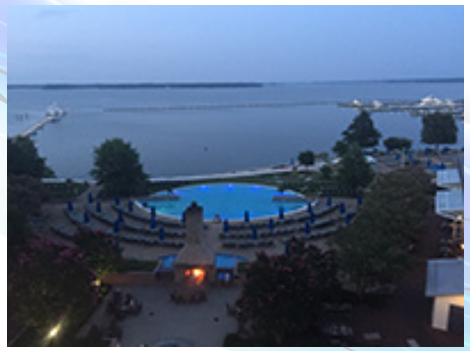
Valuable updates are also scheduled to be presented regarding FDA's Quality Management Maturity and quality culture initiatives, as well as on the various Centers' compliance groups around enforcement actions. Discussions on domestic and international regulatory trends and tools, as well as their impact 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 and agency 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.

As always, there will be plenty of networking opportunities to connect with regulators and industry experts 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

To receive emails on our upcoming programs, add reception@pharmaconference.com to your address book.

About the Speakers

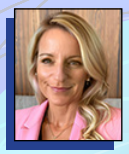
Sarah Barkow, PhD – Dr. Barkow is the Senior Director of Proactive Compliance & Innovation at AstraZeneca. In this role, she spearheads initiatives to enhance regulatory compliance and drive innovative solutions. Dr. Barkow's expertise in GxP regulatory surveillance and external engagement ensures AstraZeneca's 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.

Ileana Barreto-Pettit, RN, MPH – Ms. Barreto-Pettit is Vice President – Technical, Strategic Compliance Consulting, Parexel International. She has 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 has 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.

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.



Lynne Ensor, PhD – As a Senior Global Managing Director for NSF's Pharma Biotech Consulting and Life Sciences Training team, Dr. Ensor provides consulting support to the biopharmaceutical industry. Based on her work with the industry for over 25+ years, her expertise includes sterile product manufacturing, regulatory strategy and remediation, and compliance (cGxP). Currently, Dr. Ensor is a member of the U.S. Pharmacopeia Microbiology Expert Committee (USP 2020-2025 Council of Experts). During her 21 years at FDA, she served as the Deputy Office Director in the Office of Process and Facilities/ Office of Pharmaceutical Quality (OPQ) and on the senior leadership teams in CDER's OPQ and Office of Generic Drugs. As a regulator, Dr. Ensor authored over 60 regulatory guidances and compliance manuals on a variety of topics, including aseptic manufacturing of large and small molecule products (new, generic, biologic and biosimilars), Positron Emission Tomography, regulatory submission expectations (INDs, NDAs, ANDAs, BLAs, and DMFs), pharmacy compounding, product quality, data integrity and drug shortage prevention/supply chain integrity. She possesses extensive experience in regulatory submission expectations and remediation of non-compliance escalations (e.g., 483 observations, Warning Letters and Consent Decrees).

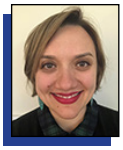
Tammy Hanley, BBA, MA – Ms. Hanley is Global Quality Auditor (GQA) for Sanofi, with a focus on GxP and Digital areas. She joined Sanofi in November 2002 as a Senior Quality Systems Analyst and Part 11 Project Manager. Over the years, she has held numerous positions in Quality and Digital Compliance. 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.

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.

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).

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.



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.

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.

Marsha Steed, BS – Ms. Steed is a globally recognized consultant specializing in sterility assurance and contamination control matters in pharmaceutical, biotech and medical device companies and has over 30 years of experience as a microbiologist working in the Pharmaceutical, Biotechnology and Medical Device fields. She is the Founder and President of Steed MicroBio, LLC, which is an independent microbiology consulting firm, and a Senior Microbiology Associate/Sterility Assurance Expert at Jeff Yuen & Associates, Inc. consulting firm. Ms. Steed is a USP Microbiology Expert Committee member and the chair of the USP Microbial Control and Sterility Assurance Subcommittee.

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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	**Current Agency Priorities** • Inspections • Domestic (on-shoring) Manufacturing Prioritization Foreign Inspection Pilots • Enforcement actions	FDA Invited
9:45 – 10:15	**Technology/Innovation (Inspection Tools)**	To Be Determined
10:15 – 10:35	Break*	
10:35 – 11:05	**Center Update: OII**	FDA, OII – Invited
11:05 – 11:35	**Center Update: CBER**	FDA, CBER – Invited
11:35 – 12:05	**Center Update: CDER**	FDA, CDER – Invited
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

This interactive workshop explores the use of mixed reality devices, such as HoloLens, in virtual audits and inspections. Building on insights from the Bill & Melinda Gates Foundation Pilot and GMP By The Sea 2022, participants will engage in hands-on demonstrations and discussions on how innovative technology enhances inspection efficiency and collaboration.

Workshop Objectives:

1. Demonstrate: how mixed reality devices facilitate virtual audits for regulators and industry.
2. Discuss: real-world applications, including lessons learned from pilot programs.
3. Engage: participants in an interactive exploration of inspection tools.
4. Brainstorm: future applications and regulatory considerations for virtual inspections.
5. Foster collaboration by sharing experiences and innovative ideas.

Workshop 2: Future of Evolving Regulatory Oversight

Sarah Barkow, PhD
FDA, CDER, OPQ – Invited

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.

Agenda

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	Workshop 3: Communicating with Regulatory Authorities: Responding to Inspection Observations and Avoiding Enforcement Actions 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.	Jennifer Bragg Ted Lis Julia Marré, PhD Industry – To Be Determined
	Workshop 4: Data Integrity (DI) • Data Governance Program • Common Deficiencies in Data Integrity • Data Integrity and its Connection to a Robust Quality Culture • Use of AI, How It Could Impact DI and How DI Impacts AI	Kir Henrici FDA, CDER – Invited To Be Determined
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	**Artificial Intelligence (AI) – Business Applications**	To Be Determined
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 – 11:40	**How Regulatory Agencies are Embracing Advanced Technologies**	FDA – Invited
11:40 – 12:10	**Question and Answer Session**	Morning Speakers
12:10 – 1:25	Lunch*	

Afternoon Workshops

1:25 – 2:55	**Workshop 1: Contamination Control:** • Aseptic Manufacturing/Annex1 • Environmental Monitoring	Marsha Steed Chris Middendorf FDA, CDER – Invited To Be Determined

Agenda

Continuing Education

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

John Hyde
Brian Stamper
FDA, CDER, OPMA – Invited

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 following areas:

- Reduction in energy consumption
- Reduction in water usage
- Reduction in waste generation

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

Tamika Cathey
To Be Determined

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

Workshop 4: FDA Remote Assessments/On-site Preparation

Ileana Barreto-Pettit
FDA, OII – Invited
To Be Determined

How do you host remote and hybrid inspections?

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**	FDA, CDER – Invited
9:10 – 9:45	**Industry Pilot Case Study**	To Be Determined
9:45 – 10:20	**Quality Culture and Emerging from Regulatory Setbacks/Challenges**	To Be Determined
10:20 – 10:40	Break *	
10:40 – 11:10	**Office of Import Operations Update**	FDA, OII, OIO – Invited
11:10 – 11:40	**CBER Compliance Update**	FDA, CBER – Invited
11:40 – 12:10	**CDER Compliance Update**	FDA, CDER, OMQ – Invited
12:10 – 12:50	**Ask FDA Q&A Session**	FDA Speakers – Invited
12:50	Closing*	

*Denotes non-educational activity

Registration

29TH ANNUAL

GMP BY THE SEA

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.

NEW GROUP DISCOUNTS!

Register 5 to 9 attendees from the same company and receive 10% off the registration price!*

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.

Cancellation Policy: 30 days or more for a full refund less $250 USD cancellation fee per registration; under 30 days, no refund, but attendee substitutions may be made at any time. Cancellations and substitutions must be made in writing to Pharma Conference (email registration@pharmaconference.com). In the event of any civil disorder, extremely adverse weather conditions, or other Acts of God, Pharma Conference reserves the right to reschedule the meeting dates in the interest of attendee safety.

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 25, 2025, in order to guarantee the special rate.** Individuals are responsible for making their own hotel reservations. **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:
Online: GMP BY THE SEA - PHARMA CONFERENCE (hyatt.com)
OR
https://www.hyatt.com/en-US/group-booking/CHESA/G-GMSE

Copy and paste the URL in your browser to make hotel reservations online or call (410) 901-1234 or (877) 803-7534.

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

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