



21st Annual GMP By The Sea

The Top GMP Conference in the U.S.

Cambridge, Maryland | August 29 – 31, 2016
Hyatt Regency Chesapeake Bay

*Featuring our popular
Maryland Eastern Shore
Dinner evening!*



Conference produced by



About the Conference

Webster defines convergence as “moving toward union or uniformity,” and this certainly applies to GMPs in the pharmaceutical and biologics industry.

Regulators are converging around the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) and **GMP By The Sea** features the group's chairman, Paul Hargreaves as a keynote speaker. Other keynotes from newly appointed CBER Director Dr. Peter Marks, CDER's Office of Pharmaceutical Quality director Dr. Michael Kopcha, and Assistant Commissioner for Operations Ellen Morrison will demonstrate FDA's converging approach to quality.

The industry is also facing the challenges of consolidation. Key corporate leaders will discuss the challenges of merging systems and cultures.

Other plenary sessions, fully described in the agenda, include data integrity, FDA investigator training, and a special “Ask CDER” session where you can receive answers to YOUR questions.

The unique workshop format at **GMP By The Sea** is always a highlight. Eight breakout sessions provide an opportunity to learn from FDA experts and industry colleagues informally. These are repeated, so you can attend two of the five offered each afternoon. With topics such as quality culture, shared compliance, data integrity auditing, and process validation, this opportunity will meet your most critical needs. Attendance by your whole organization will assure coverage of the many important subjects.

Each session includes time for questions and answers, but there are also opportunities for informal, one-on-one interaction with regulators and peers during breaks, a Monday night networking reception, and a Tuesday evening traditional Maryland Eastern Shore dinner.

GMP By The Sea has always been considered the premier event of its kind, with unmatched opportunities to learn from and meet senior government and industry experts. Attendance by your whole team will prove why this is THE ONE conference many attend every year.

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.

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 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

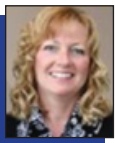
About the Speakers



Diane Alexander, BS, MT(ASCP)SBB – Ms. Alexander serves as the Associate Director for Regulatory Policy with the Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research where she is responsible for policy development and review. She began her service with FDA in 1995 and worked as a compliance officer for 10 years and then six years as a Branch Chief where she was responsible for the review and evaluation of administrative and legal actions for biological drugs and devices regulated by CBER. Prior to joining FDA, Ms. Alexander was employed as a Medical Technologist in the Washington Hospital Center's Blood Bank.



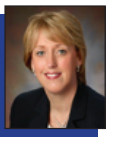
Gary Bird, PhD – Dr. Bird is currently President, PharmaConsult-US, LLC, and Managing Partner, PharmaConsult Global, Ltd., an international cooperative supplying GXP quality consulting services. He served as Director of Corporate Quality for GTx, Inc. (Memphis, TN, USA) from 2003 until 2013 and was responsible for confirming all non-clinical (GLP), manufacturing (GMP), and clinical trial (GCP) related activities were conducted in compliance with appropriate laws and regulations. He has held previous positions with Eli Lilly and the FDA where he represented both PhRMA and the FDA in the International Conference on Harmonization negotiations on four (4) different agreed guidances.



Karen Biscardi, MS, RAC – Ms. Biscardi is a Senior Regulatory and Quality Assurance Consultant with Tunnell Government Services, supporting the Biomedical Advanced Research and Development Authority (BARDA), Office of the Assistant Secretary for Preparedness and Response (APSR), and the U.S. Department of Health and Human Services (HHS). She has 23 years previous experience within the vaccine industry and has earned eight patents for innovative research supporting new and existing vaccine products during her seven years experience within R&D. Ms. Biscardi has 20 years of experience within Regulatory Affairs. In her previous position, she was the North American Head of Regulatory CMC and had management responsibility for the regulatory activities related to marketed products, including influenza virus vaccines and pandemic influenza vaccines. In this role, she managed the regulatory activities leading to the successful registration of the first U.S. licensed pandemic influenza virus vaccine in 2007. She also managed the regulatory activities leading to successful licensure of the nation's largest inactivated influenza virus vaccine manufacturing facility.



Thomas Cosgrove, BS, JD – Mr. Cosgrove is the Director of the Office of Manufacturing Quality (OMQ) within FDA's Center for Drug Evaluation and Research (CDER). In this role, he directs CDER's compliance activities with respect to CGMP and product quality. Before OMQ, Mr. Cosgrove led CDER's Office of Unapproved Drugs and Labeling Compliance (OUDLC), where he was responsible for FDA's compliance divisions covering drug approval and labeling issues. Before joining CDER, he was a litigator in FDA's Office of Chief Counsel, and prior to FDA, he was an attorney at Covington & Burling in Washington, D.C.



Jacqueline Elbonne, PhD – Dr. Elbonne is Senior Vice President, Global Quality at Merck & Co., Inc. She is responsible for overseeing the quality and compliance of global manufacturing operations for Merck's medicines and vaccines for both the human and animal health businesses. Her responsibilities also include global quality oversight of external supplier's and manufacturing operations as well as research and commercialization activities for the development, approval and launch of new pharmaceuticals, vaccines, and biologics. Previously, Dr. Elbonne was with Schering-Plough starting in 2001. In 2004, she became Vice-President of Pharmaceutical Sciences Quality, and in 2008 she was appointed Vice-President of Global Research Quality for the entire Schering-Plough Research Institute. In 2009, Schering-Plough merged with Merck & Co., Inc. and Dr. Elbonne was appointed as Merck's Vice President of Research & Commercialization Quality.



Mark Elengold, BA – Mr. Elengold is President of FDA Strategies LLC, which provides consulting services to FDA regulated industry and the financial community. He retired as the Deputy Director of the FDA's Center for Biologics Evaluation and Research after 34 years of service. He is an expert and frequent speaker on regulatory and compliance activities, Good Manufacturing Practices (GMPs), and FDA application review procedures, including electronic submissions.



Paul Hargreaves, MSc – Mr. Hargreaves became Chair of the Pharmaceutical Inspection Convention/Pharmaceutical Inspection Co-operation Scheme, (PIC and PIC/S respectively) on 1st January 2016 and will hold the post for two years. He is an Expert Medicines Inspector who spent 12 years in the pharmaceutical industry prior to joining MHRA in 1986. He has inspected most types of medicines, from herbals to biotechnology medicines both in the UK and overseas. For the past two years Mr. Hargreaves has worked as liaison manager between the Inspection Group and the Enforcement Group.

About the Speakers



Lori Hirsch, BA, JD – Ms. Hirsch is Managing Counsel for Merck & Company, Inc., where she represents Merck's global manufacturing division on a variety of matters, including those involving pharmaceuticals, vaccines, biologics, OTC, and animal health products. For the past 15 years, she has specialized in compliance matters, with an emphasis on cGMPs, and today leads a legal team with cGMP expertise.



John Hyde, BS, BBA, MS – Mr. Hyde is Chairman and Founder of Hyde Engineering + Consulting, Inc., a firm of 220+ engineers and scientists, founded in 1993 and specializing in process engineering, process and equipment validation, and compliance consulting for biopharmaceutical and pharmaceutical manufacturers. The company has operations in the United States, Europe, Singapore and India. For nearly two years prior to the formation of Hyde Engineering + Consulting, Inc., Mr. Hyde was Senior Project Engineer with Synergen, a biopharmaceutical research and manufacturing company. From 1982 to 1992, Mr. Hyde was Manager, Process Design with Seiberling Associates, Inc., an engineering firm specializing in the design and start-up of biopharmaceutical, food and beverage process systems and the application of CIP technology.



Robert Iser, MS – Mr. Iser joined the FDA in 2003 and is currently the Acting Director of the Office of Process & Facilities (OPF), a part of the new Office of Pharmaceutical Quality (OPQ). Prior to the formation of OPQ, he was acting Associate Director for Policy Development in the Office of Pharmaceutical Science. He was also a Division Director and CMC Team Leader in the Office of Generic Drugs. Prior to joining the FDA, Mr. Iser spent seven years in the pharmaceutical industry with industrial experience related to management of quality systems, analytical method development, and support of manufacturing process development, scale-up and validation.



Michael Kopcha, PhD, RPh – Dr. Kopcha is Director, Office of Pharmaceutical Quality, FDA. He is a leader in the development of innovative solutions to resolve scientific, manufacturing, and commercialization issues worldwide – and in standardizing and harmonizing global processes. With more than 25 years of pharmaceutical industry experience, his areas of expertise include formulation and process development, process validation, technology transfer, off-shoring/outsourcing, and change management. Dr. Kopcha recently served as vice president, and global research and development franchise head, for cough, cold, and respiratory products at Novartis Consumer Health, Inc. in New Jersey. He joined Novartis in 2008 as the global head for pharmaceutical and analytical development, later serving as global head for new technologies and product innovation, and vice president and global head for global product development. Before joining Novartis, Dr. Kopcha served as vice president for pharmaceutical development at KV Pharmaceutical, Inc. in St. Louis. His experience also includes related roles with Schering-Plough, J&J, and Ivax.



James Little, BS, MS – Mr. Little joined BARDA (Biomedical Advanced Research and Development Authority) in August 2010 as a Regulatory Specialist. Since January 2014, he has served as Deputy Director of the Regulatory and Quality Affairs Division where he manages a staff of highly experienced regulatory and quality subject matter experts. These experts provide guidance to external partners and internal BARDA teams to minimize the inherent regulatory process risks associated with the development and/or acquisition of medical countermeasures. Prior to joining BARDA, Mr. Little was a consultant in regulatory affairs and compliance at Aclairo Pharmaceutical Development Group where he provided nonclinical program development expertise, regulatory affairs, compliance, and due diligence services for clients seeking development of drugs, devices or biologics. Before moving to the D.C. area, Mr. Little worked in the private sector primarily focused on toxicology and nonclinical development for FDA-regulated products.



Mary Malarkey, BS – Ms. Malarkey is the Director, Office of Compliance and Biologics Quality (OCBQ), at FDA's Center for Biologics Evaluation and Research (CBER). From 2000 through 2004, she was the Director, Division of Case Management (DCM), OCBQ, CBER. Prior to that, Ms. Malarkey was a Branch Chief in the Division of Manufacturing and Product Quality (DMPO), CBER. She worked in Research and Development in industry prior to joining FDA, and has been with CBER since 1989.



Peter Marks, MD, PhD – Dr. Marks is Director, Center for Biologics Evaluation and Research (CBER), FDA, a position he was named to in early 2016. He joined the FDA in 2012 as Deputy Center Director for CBER. Prior to joining FDA, Dr. Marks worked for several years in the pharmaceutical industry on the clinical development of hematology and oncology products prior to returning to academic medicine at Yale University where he led the Adult Leukemia Service and served as Chief Clinical Officer of Smilow Cancer Hospital. Before that, he joined the attending staff of Brigham and Women's Hospital in Boston as a clinician-scientist and eventually served as Clinical Director of Hematology. Dr. Marks is board certified in internal medicine, hematology and medical oncology, and is a Fellow of the American College of Physicians.

Register online at www.pharmaconference.com

About the Speakers



Melissa Mendoza, JD – Ms. Mendoza is an Associate Chief Counsel for Enforcement at FDA's Office of the Chief Counsel. Since 2008, she has handled various types of civil enforcement actions brought by FDA in conjunction with the Department of Justice, including injunctions, seizures, actions for civil money penalties, and contempt actions. Ms. Mendoza advises FDA personnel on matters concerning interpretation, application, and enforcement of the Federal Food, Drug, and Cosmetic Act and its implementing regulations and provides legal advice regarding inspections, warning letters, recalls, and import detentions.



Ellen Morrison, BA – Ms. Morrison is the Assistant Commissioner for Operations in the Office of Regulatory Affairs at the Food and Drug Administration (FDA) where she leads a team serving as the focal point for coordination and management of ORA's field activities, including the approval and issuance of assignments from headquarters and centers. The Office of Operations provides direction to field scientific resources, field import operations, and serves as the contact point to the U.S. Customs Service and other federal agencies involved in import activities. assignment at the Center for Biologics Evaluation and Research. In 2002, FDA named Ms. Morrison the Director of Emergency Operations, Office of Crisis Management, where she directed and coordinated FDA's emergency preparedness and response activities with other federal, state, local, and international agencies. In 2003, she became the first Director of the newly established Office of Crisis Management, where she advanced the priorities of the Commissioner through development and management emergencies, crisis management, and security policies and programs for FDA. Ms. Morrison returned to the Office of Regulatory Affairs in 2012 as the Acting Assistant Commissioner for Operations and a year later was named



Timothy Oswald, BA – Mr. Oswald is the Manager, Project Services for The Quantic Group, where he has worked for over 18 years. The Quantic Group is a pharmaceutical management consulting firm, providing technical resources to manufacturing organizations in the areas of quality, production and compliance. Mr. Oswald is responsible for overseeing all resource assignments for the firm. His skills include IT planning and system specification, technical specification and user requirements planning, and IT system program management and controls.



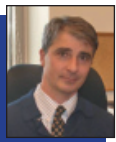
Michael Plover, BA – Mr. Plover is Senior Associate in the Lachman Consultants' Compliance Practice who brings Lachman Consultants' clients more than 40 years of experience in the quality arena, specializing in pharmaceutical, dietary supplement, and medical device compliance. Mr. Plover supports regulatory inspections, performs quality systems audits for pharmaceuticals, dietary supplements, and medical devices, and implements systems to comply with the various GMP regulations. Additionally, he is highly skilled in remediation planning and implementation.



Edwin Rivera Martinez, BA, MBA – Mr. Rivera Martinez is Vice President, U.S. Quality Liaison, Global Quality for Sanofi, a position he has held since January 2012. He serves as the focal point between Chief Quality Officer in Sanofi, the FDA, professional associations and internal quality entities in the United States. Before joining Sanofi, he worked with PAREXEL as a Vice President, Technical, providing cGMP compliance services to clients in the United States, Europe and Japan. Previously, he worked with the U.S. FDA for 33 years, most recently as the Branch Chief, International Compliance Branch, in CDER's Office of Compliance where he was responsible for the group reviewing inspection reports of human drug inspections conducted outside of the United States. He also served as the Branch Chief for the Manufacturing and Preapproval Compliance Branch where he managed the human drug pre-approval inspection program in CDER for 10 years.



Richard Schoenfeld, PhD – Dr. Schoenfeld is the principal of BioWorks Consulting, a consulting practice that specializes in developing and manufacturing proteins through cell culture processes as well as review of existing operations, strategic planning, plant and process design. He has over 40 years of process development and manufacturing experience. His area of technical expertise is the scale-up of mammalian cell culture processes. He has previously been Vice President of Operations for PharmAthene, Vice President, Supply Chain Management at EMD Pharmaceuticals (Merck, KGaA of Darmstadt, Germany), Senior Vice President, Engineering and Technology Development, at Genzyme, and held positions at Endotronics and Monsanto where he developed mammalian cell culture technology and plasma fractionation methods.



Douglas Stearn, JD – Mr. Stearn is the Director of the Office of Enforcement and Import Operations at ORA/FDA. Prior to this, he served as Deputy Director for Policy and Analysis within the Office of Compliance, CDER. In this position, he was responsible within CDER for developing compliance policy and responding to compliance policy issues, as well as overseeing the office's review of legal and informatics issues. Prior to joining CDER, Mr. Stearn served in FDA's Office of Regulatory Affairs as the Director of the Division of Compliance Policy and the Acting Director of the Office of Enforcement. Prior to joining FDA, Mr. Stearn was a trial attorney for 15 years in the Office of Consumer Litigation in the U.S. Department of Justice where he litigated criminal and civil issues arising under the Federal Food, Drug, and Cosmetic Act and other consumer protection statutes.

About the Speakers



Karen Takahashi, BS, MS – Ms. Takahashi is a Senior Policy Advisor in CDER's Office of Pharmaceutical Quality in the Office of Policy for Pharmaceutical Quality. Prior to January 2015, she spent 15 years as a Senior Policy Advisor and a Compliance Officer in CDER's Office of Manufacturing and Product Quality. At the beginning of her FDA career, Ms. Takahashi was an Investigator with FDA's New England District Office.



Carolyn Trott, BS – Ms. Trott is Head of Quality for Sanofi Specialty Care (EU/Asia). She has 25 years of experience in Biologics, including manufacturing, validation, regulatory affairs, and quality assurance. Prior to her current position, Ms. Trott was Vice President of Corporate Quality Operations for Genzyme, responsible for the development and implementation of Genzyme Quality Standards, deployment of quality risk management program and tools, global validation, stability and statistics programs, CMO management, management of the product complaint program, as well as development and management of the quality/regulatory intelligence and inspection observation sharing programs. She was also the Genzyme lead for the integration of the quality system with Sanofi when Sanofi acquired Genzyme in 2011. Prior to Genzyme, Ms. Trott had various roles in manufacturing and validation for Immunogen, Raytheon Engineers and Constructors, and Jacobs Engineering.



Brandon Varnau, BS – Mr. Varnau is Vice President and Head of Operations Quality for Sanofi Specialty Care (US and Belgium Sites). He utilizes 24 years of experience in Biologics to lead all aspects of Quality Assurance, Quality Control and Compliance for eight Biologics and Biosurgery sites in the US and EU. Prior to his current position, Mr. Varnau was Vice President of Quality at Genzyme's Allston plant, where he joined Genzyme in 2011 just after this site received a FDA consent decree. Prior to Genzyme, Mr. Varnau was Vice President of Quality for Bayer Health Care.



Peter Watler, PhD – Dr. Watler is Chief Technical Officer Coherus Biosciences and has more than 32 years of biopharmaceutical process development and manufacturing experience. He has deep knowledge of the development and scale-up of biopharmaceutical processes such as fermentation, centrifugation, filtration, and chromatography. His skill set spans process modeling, economic analysis, manufacturing operational excellence, process control and validation. His regulatory experience includes co-authoring two IND submissions, four BLA submissions, and participation in several FDA inspections and GMP audits. Prior to his position at Coherus, Dr. Watler most recently served as Chief Technology Officer of Hyde Engineering + Consulting, Inc. He has also served as Associate Director of Process Engineering with Amgen and Vice President, Manufacturing at VaxGen, a Genentech spinoff formed to develop an AIDS vaccine.



Fran Zipp, BSc – Ms. Zipp is President & CEO of Lachman Consultant Services, Inc. Lachman Consultants provides compliance, regulatory and technical consulting services to the global pharmaceutical and related industries, and Ms. Zipp delivers the strategic guidance and direction toward implementation of effective solutions to client needs. As an expert in compliance enhancement, she develops program solutions to meet GXP compliance requirements. Ms. Zipp has extensive experience in the pharmaceutical, biologic and biotechnology industries from R&D through post-market approval. She assists and counsels senior-level management in areas of Corporate Governance, Corporate Integrity Agreement Compliance, Consent Decree Negotiations and Resolutions, Application Integrity Policy resolution, Due Diligence evaluations (facilities; products; technologies), and more.

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 in 2002 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 74 miles southeast of BWI Airport, 90 miles southeast of Ronald Reagan Washington National Airport, and 95 miles southeast of Dulles. For exact directions to the hotel, please log on to

<http://chesapeakebay.hyatt.com/hyatt/hotels/services/maps/index.jsp?icamp=propMapDirections>



Register online at www.pharmaconference.com

Agenda

Monday, August 29, 2016

Morning Session: Moderator – Mark Elengold, Conference Chairman

8:00 – 9:00	Registration	
9:00 – 9:10	Welcome	
9:10 – 9:50	Keynote: PIC/S	Paul Hargreaves, MHRA
9:50 – 10:30	Keynote: Establishing and Sustaining a Culture of Quality Compliance	Jaqueline Elbonne, PhD
10:30 – 10:50	Break*	
10:50 – 11:35	Maintaining Quality Culture in a Landscape of Outsourcing	Peter Watler, PhD
11:35 – 12:10	The Quality and Technical Challenges of Continuous Processing	Richard Schoenfeld, PhD
12:10 – 12:30	Question and Answer Session	Morning Speakers
12:30 – 1:45	Lunch*	

Afternoon Session: Workshops

1:45 – 3:15	Workshop 1: Enhancing and Sustaining Corporate Culture/ Auditing for a Quality Culture	Fran Zipp
	Workshop 2: Data Integrity – Code of Conduct	Lori Hirsch
	Workshop 3: Applying Concepts of Quality By Design to Multiple Product Types	Speaker TBA
	Workshop 4: Lessons Learned in Applying cGMPS for Products Used in a Public Health Emergency	Karen Biscardi, BARDA James Little, BARDA
3:15 – 3:35	Break*	
3:35 – 5:05	Workshops Repeated – the above workshops will be repeated	
5:30 – 7:30	Networking Reception* Drinks and hors d'oeuvres for two hours	

Tuesday, August 30, 2016

Morning Session: Moderator – Diane Alexander

9:00 – 9:30	Keynote – ORA	Ellen Morrison, ORA
9:30 – 10:00	Keynote – CBER	Peter Marks, MD, PhD, CBER
10:00 – 10:30	Keynote – CDER	Michael Kopcha, PhD, RPh, CDER
10:30 – 10:50	Break*	
10:50 – 11:20	Shared Compliance – Understanding/implementing 483 Observations	Carolyn Trott, Sanofi
11:20 – 11:50	Data Integrity and How is FDA Training Investigators and Establishing Criteria	Rebecca Rodriguez, ORA Invited

Agenda

11:50 – 12:30 **Question and Answer Session**
12:30 – 1:45 Lunch*

Morning Speakers

Afternoon Session: Workshops

1:45 – 3:15 Workshop 1:
**Fostering Compliance with GxP Regulatory Requirements
With a Formalized Proactive Process For Sharing Inspection
Outcomes and Findings**

Brandon Varnau
Edwin Rivera-Martinez
Carolyn Trott

Workshop 2:
A Practical Approach to Identifying Data Integrity Issues

Gary Bird, PhD
Timothy Oswald
Rebecca Rodriguez, ORA Invited
Karen Takahashi, CDER

Workshop 3:
The Technical Issues of Process Validation

John Hyde and Peter Watler, PhD

Workshop 4:
**The Sustainable Culture: CAPA (Root Cause Analysis,
Process Validation, Deviations)**

Michael Plover

3:15 – 3:35 Break*

3:35 – 5:05 **Workshops Repeated – 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.

Wednesday, August 31, 2016

Morning Session: Moderator – Diane Alexander

8:30 – 9:00 **Office of the Chief Counsel Update**
9:00 – 9:30 **Current CBER Compliance Initiatives**
9:30 – 10:00 **Office of Enforcement Update**
10:00 – 10:20 **Question and Answer Session**
10:20 – 10:40 Break*
10:40 – 11:10 **CDER Office of Compliance Update**

11:10 – 12:15 **Ask CDER Q&A Session**

Melissa Mendoza, OCC
Mary Malarkey, CBER
Douglas Stearn, ORA

Thomas Cosgrove, CDER
Robert Iser, CDER
Thomas Cosgrove, CDER
Michael Kopcha, PhD, RPh, CDER

**Denotes Non-Educational Activity*

Register

21st Annual GMP By The Sea

Fees

 *Register early and SAVE!*

	<u>Industry</u>	<u>Gov't & Press</u>
Payment Received By June 17, 2016	<input type="checkbox"/> \$2095	<input type="checkbox"/> \$1395
Payment Received After June 17, 2016	<input type="checkbox"/> \$2295	<input type="checkbox"/> \$1395

Includes conference, continental breakfast, breaks, lunches, networking reception and evening social per agenda.

Cancellation Policy: 30 days or more for a full refund less \$250 cancellation fee; 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

Full payment may be made by credit card or company check

- Checks must be received within 15 days of receipt of registration form.
- Checks should be made payable to Pharma Conference Inc, in U.S. dollars and drawn on a U.S. bank.
- Registrations will be confirmed when full payment has been received. Taxpayer ID #27-1438344.
- Registrations made within 30 days of conference start date must be accompanied by full payment.

Checks should be sent to Pharma Conference Inc at the following addresses (see check instructions above):

Airmail to: P.O. Box 291386, Kerrville, Texas 78029 USA

Express to: 819 Water Street, Suite 350, Kerrville, Texas 78028 USA

Hotel

Hyatt Regency Chesapeake Bay
100 Heron Blvd., Cambridge, MD 21613
Direct Phone: (410) 901-1234
\$223 single/double

A limited number of rooms have been blocked at the special rates listed per night. **Hotel reservations must be made on or before August 12, 2016, 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.**

For additional information, contact Pharma Conference Inc:
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