The top GMP conference in the U.S.!

25TH ANNUAL GMP BY THE SEA

AUGUST 9 – 11, 2021
CAMBRIDGE, MARYLAND

Special anniversary discounts!

REGISTER EARLY AND SAVE $200!

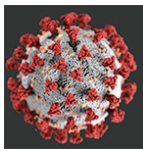
Conference produced by

PHARMA CONFERENCE INC

The top producer of premier pharmaceutical conferences for the past 26 years

Featuring our popular Maryland Eastern Shore Dinner evening!

Click here for more information



COVID-19 RESPONSE

About the Conference

25 years of **GMP By The Sea**. Twenty-five years of topics from FDA, PIC/S, EMEA, Industry, and Canada's HPB. 25 years of cutting edge discussions, networking, making friends and contacts, talking face-to-face with the same FDA leader you read about in the news, over 100 workshops, and evening socials with tons of crab, fish, steak, veggies galore, and desserts you cannot believe. Finally, 25 years of watching the evolution of the GMPs. That and more has happened during our previous 24 years of **GMP By The Sea**.

David Chesney will open our celebration of the 25th anniversary of **GMP By The Sea** by discussing the evolution of GMPs which many of us have lived. Then, with an eye to the next 25 years, Peter Marks, MD, PhD, Director of CBER, FDA (invited); Donald Ashley, Director of CDER's Office of Compliance, FDA (invited); Judith McMeekin, PharmD, Acting Associate Commissioner for Regulatory Affairs (ACRA), ORA, FDA (invited); and Alonza Cruse, Director of the Office of Pharmaceutical Quality Operations, ORA, FDA (invited); will focus on some of the most critical issues facing FDA with a focus on the advent of new technologies and current gaps, talks designed to help you dive deeply into GMPs to anticipate the ever-evolving concerns of the regulators.

Industry speakers will turn our attention to issues facing companies of all sizes. Doug Farquhar (Hyman, Phelps & McNamara, PC) and Raymond Bonner (Sidley Austin LLP) will provide a "ripped from the headlines" analysis of the need for proactive compliance using the recent N-nitrosodimethylamine (NDMA) episodes as a case study in their inimitable styles. (It should be noted that these two well-known attorneys could charge up to $1500 for just one hour of consultation; however, you get it as part of the program.) Advances in technology will be addressed by Gary Dodakian from Sanofi (continuous manufacturing) and another industry leader (the future of Artificial Intelligence), while Timothy Martin, PhD (CBER, FDA) will turn the focus to the CGMP for Cell and Gene Therapy Products in his comprehensive workshop. We will also focus our attention to some of the most pressing GMP concerns facing the industry with talks intended to focus on Proactive Compliance (Shane Yount, Competitive Solutions Inc) and Coaching Leadership and Quality (Steve Greer, Genesis Assist, LLC).

This year, as in the past, interaction with the regulatory authorities will be one of our best tools for learning. The *Bring Your Own GMP Questions* will allow you to address your own specific questions and concerns. Too bashful to ask a question in public? Our numerous opportunities for interaction and networking will help you meet others from both industry and FDA who can help. New directions in regulatory activities will also be discussed, which will provide you and your company a leg up on the competition.

Our very popular workshops allow you to customize your conference experience by providing four different workshop tracks. We will be offering half-day sessions in Biotech, Contract Manufacturing, Education and Training, Laboratory Issues, and Parenteral Manufacturing. By offering repeating workshops on Monday and Tuesday, each participant will be able to attend two different workshop sessions each day to get the maximum from the program.

In keeping with Pharma Conference's commitment to keep the program new and fresh every year, we are adding two new extra-curricular activities:

1. Plan to join FDA Investigators in our new Breakfast with FDA Investigators. In this informal setting, you will be able to ask the questions you have always wanted to ask of the investigators and get answers on the spot from the very people who conduct the inspections and write the 483s.
2. A FREE two-hour workshop will be offered by John Avellanet, Auditing for Data Integrity like an FDA Investigator, at the conclusion of the regular program on Wednesday. This opportunity to listen to the trainer who trains the trainers will be unlike many similar programs in that you will listen to the acknowledged expert in the field of data integrity auditing and remediation.

This conference is the best opportunity you will have in 2021 to meet new industry professionals and to interact with FDA, plus enjoy some fun activities to celebrate our milestone 25th anniversary. Make sure to register early to save money and secure your spot.

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

Bonus Post-Conference Workshop: Auditing for Data Integrity like an FDA Investigator

with John Avellanet, Cerulean Associates, LLC

Whether you audit – or need to prepare your firm (or critical suppliers) to be inspected – this post-conference workshop will give you the techniques and knowledge to help avoid public trouble and internal confusion. Taught by one of the trainers for the US FDA with more than 20 years of experience, you will:

- Learn what FDA investigators understand about data fraud and how to uncover it
- Recognize items to keep an eye out for during your initial walk through at a supplier or an internal site that alert you to dig deeper into data integrity controls
- Understand how to use the NIPP to help you audit – and to help your firm better prepare for any ICH inspection (FDA, EMA, Health Canada, etc.)
- Identify the specific red flags to look for when reviewing SOPs and policies that FDA is trained to scrutinize
- Be able to skim through computerized system validation documentation to quickly look for data integrity control verifications
- and much more!

This post-conference workshop is designed to be full of practical and pragmatic advice with working knowledge and tools you can use immediately. Attendees should have at least a basic understanding of data integrity and its criticality to 21st century compliance.

Sign up for this free workshop when you register online for GMP By The Sea.

About the Speakers

John Avellanet, MS – Mr. Avellanet is the founder of Cerulean Associates, LLC, which provides training for FDA and Health Canada inspectors and district officers on advanced data integrity inspection techniques and detecting data fraud. He has served on behalf of the US Department of Justice as the independent overseer for corporate integrity agreements, been the industry reviewer for multiple international standards, and authored several books. Prior to founding Cerulean, Mr. Avellanet spent more than 15 years designing, implementing, and being accountable for quality systems and data compliance programs for FDA, DEA, BIS, ICH, IMDRF, and ISO.

Gary Bird, PhD – Dr. Bird is currently Senior Vice President, Quality Oversight, Veru, Inc. Formerly, he was 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.

Brian L. Bishop, PhD – Dr. Bishop is Director, Regulatory Affairs at Emergent BioSolutions where he serves as an expert on regulatory impacts to commercial vaccines, medical countermeasures, and public health emergency preparedness. He draws on 20 years in the academic sciences, research administration, and biologics manufacturing to transform global regulatory strategy into practical, commercial visions. He has conducted seminars across the country on infectious disease and select agent pathogenesis. As a member on the ATCC Standards Development Organization he served as an expert on anthrax toxins.

Jeffrey Carter, BS – Mr. Carter is Director, Quality Systems & Compliance within the Global Quality Compliance organization at Merck and draws on over 24 years of biopharma experience in areas of Quality Control, Quality Assurance, Project Management, Quality Shop-Floor Support/Management, Sterile Supply, Product Release and Quality Systems Management. He recently led development, IT enablement, deployment and global implementation of an innovative Deviation Management Quality System at Merck's Human Health manufacturing facilities. Previously, Mr. Carter was Associate Director, Quality Systems & Compliance with leadership of a Merck Vaccine manufacturing facility's Product Quality Complaints (PQC), Adverse Events (AEs), Deviation Management and CAPA Quality Systems.

David L. Chesney, BS, MSJ – Mr. Chesney is the Principal and General Manager for DL Chesney Consulting, LLC. Previously, he served for over 20 years as Vice President, Strategic Compliance Services for PAREXEL Consulting. Prior to joining PAREXEL Consulting, Mr. Chesney served 23 years with the FDA. He holds an MS in Pharmaceutical and Medical Device Law from Seton Hall University School of Law and a Bachelor's degree in Biology from California State University, Northridge.

Armando Cortes, BS – Mr. Cortes is a pharmaceutical operations and biotechnology executive with over 30 years of experience in the pharmaceutical industry and a recognized record of success in Quality and Manufacturing operations in small volume parenteral, API and solid oral dosage forms. He is the Vice President Quality at Nabriva Therapeutics, Inc. Mr. Cortes's experience spans leading and managing traditional and multicultural work environments in domestic (US) and/or international settings. He is a graduate of Drexel University's College of Engineering and is a member of the Parenteral Drug Association (PDA) and the International Society of Pharmaceutical Engineers (ISPE).

Thomas J. Cosgrove, MA, JD – Mr. Cosgrove is a partner in Covington & Burling LLP's Food, Drug and Device Practice Group. He joined Covington in 2017 from the Food and Drug Administration (FDA), where he was a senior official charged with ensuring the quality of drugs and therapeutic biologics marketed to U.S. patients. Mr. Cosgrove brings a wealth of experience to bear in helping clients navigate the complex world of pharmaceutical compliance and enforcement in the United States and around the globe.

FDA

Alonza Cruse, BS – Mr. Cruse is Director of the Office of Pharmaceutical Quality Operations within the FDA Office of Regulatory Affairs. The office is responsible for all pharmaceutical inspections, working in conjunction with FDA's Center for Drug Evaluation & Research and Center for Veterinary Medicine. From 2013-2015 Mr. Cruse served as the Director (Acting) of the Office of Medical Products & Tobacco Operations within ORA. From 2000-2015, he was the Director of FDA's Los Angeles District Office. Prior to this, Mr. Cruse was Director of New York District Import Operations. He first joined ORA in 1983 as a microbiologist.

FDA INVITED

Robert Darius, BS – Mr. Darius is the Head of Injectables Compliance at Sanofi. Previously, he served as SVP Quality Unit at Novavax Vaccines. Prior to that, he was VP Global Quality Unit in GSK Vaccines for North America and Germany for 11 years. Mr. Darius started Radius Biotechnology, LLC, a biotechnology consulting firm, after serving in the FDA Center for Biologics Evaluation and Research for 15 years as Lead Reviewer & Inspector. He also served as Special Assistant on Counter Bioterrorism issues, reporting to the CBER Director. Mr. Darius is a Microbiologist by training and attended George Mason and Johns Hopkins Universities.

About the Speakers

Gary Dodakian, MA – Mr. Dodakian is the Site Quality Head, Framingham Biologics for Sanofi. He is responsible for ensuring that effective quality systems and processes are in place to assure high product quality and compliance with current cGMPs for multiple rare disease products and the build out of Sanofi's new multi-product, continuous manufacturing facility. Prior to Sanofi, Mr. Dodakian held various leadership positions related to QC, QA, manufacturing, development and technical support at Bristol Myers Squibb.

David Doleski, BS – Mr. Doleski is the Compliance Head, Biologics Quality Operations for Sanofi. He is responsible for ensuring site readiness for inspections and conformance to regulatory expectations. Prior to Sanofi, Mr. Doleski served in FDA for over 27 years, where he progressed through leadership positions related to FDA's inspection and review programs for drugs and biologics. His last position in FDA was Acting Deputy Director for the Office of Process and Facilities (OPF), which is an office responsible for performing pre-approval inspections and application reviews. He led efforts to integrate those diverse quality assessment activities prior to application approval.

Douglas B. Farquhar, BA, JD – Mr. Farquhar is Director, Hyman, Phelps & McNamara, P.C., the most prominent U.S. firm for medical device and pharmaceutical product regulation and enforcement. He has more than 30 years of experience as a prosecutor and defense and regulatory attorney. Since 1997, when he joined the firm, he has advised pharmaceutical and medical device manufacturers and wholesalers, compounding pharmacies, and individuals on a wide range of enforcement activities. Mr. Farquhar has a broad-based understanding of the investigatory process, having negotiated settlements and resolutions for both industry and government. He also advises companies and individuals on adverse findings after FDA and other regulatory agency inspections. He was an assistant U.S. Attorney in the District of Maryland from 1990 to 1997.

Steve Greer, BS – Mr. Greer is Executive Coach, Speaker & Consultant with Genesis Assist, LLC. An engaging and inspiring keynote speaker and executive coach working with Fortune 50 to small businesses, he speaks on improving performance, increasing employee engagement, and leading change. He speaks at both international and domestic conferences serving many sectors including consumer goods, pharmaceuticals, banking, etc. Mr. Greer recently completed a 35-year career at the Procter & Gamble Company where he last served as the External Engagement Leader in Corporate Quality Assurance. In this role he was responsible for building collaborative relationships with boards of health and industry as well as strengthening internal GMP capability. Mr. Greer is on the core team of the ISPE Advancing Pharmaceutical Quality initiative. He is also co-chair of the Quality Assurance Committee of the Personal Care Products Council and previously served as the chairman of the Pharmaceutical Industry Association of Puerto Rico's QA committee.

Maik W. Jornitz, MEng – Mr. Jornitz, President and CEO of G-CON Manufacturing Inc., is a technical expert with over 30 years of experience in bioprocesses, especially sterilizing grade filtration and single-use technologies, including regulatory requirements, integrity testing, systems design, and optimization. He has published 11 books, 18 book chapters, and over 100 scientific papers. He is the former Chair of the PDA Board of Directors and Science Advisory Board, and member of multiple PDA Task Forces. He is a working member of BPOG, ASTM, an advisory board member of the Biotechnology Industry Council, ICAV and multiple science journals. He recently has been recognized as one of the top 10 global industry influencers. As a faculty member of various training activities, including PDA TRI, he trains members of the industry and regulatory authorities on a frequent basis.

FDA

Scott J. MacIntire, BS – Since November of 2014, Mr. MacIntire has been the Director of the Division of Enforcement at FDA's Office of Regulatory Affairs (ORA). He works closely with the ORA field divisions and FDA centers in determining voluntary and regulatory strategies for follow up action. He also serves as the Agency focal point for guidance on recall plans and procedures, directs and coordinates ORA's activities related to the investigation of health fraud, and provides management and oversight of the Agency's debarment program. Mr. MacIntire is currently an advisor to the Strategic Coordinated Oversight of Recall Execution (SCORE) team which was formed as an Agency response to the OIG Food Recall Study. Prior to his current position, he was Director of the Chicago District Office from 2004 to 2014. He has worked in the field of public health protection for the past 37 years, 30 of those years with the FDA.

FDA

Jennifer A. Maguire, BS, PhD – Dr. Maguire is the Deputy Director of the Office of Quality Surveillance/ OPQ/CDER/FDA, which assesses intelligence throughout the product lifecycle to inform stakeholders about the state of pharmaceutical quality. During her tenure, Dr. Maguire has contributed to initiatives aimed at modernizing the regulation of pharmaceutical manufacturing and product quality including QbR, QbD, ICH Q12, Site Selection Model, Quality Metrics and Quality Management Maturity.

FDA

Peter Marks, MD, PhD – Dr. Marks is Director, Center for Biologics Evaluation and Research, FDA. He received his graduate degree in cell and molecular biology and his medical degree at New York University and completed Internal Medicine residency and Hematology/Medical Oncology training at Brigham and Women's Hospital in Boston. He has worked in academic settings teaching and caring for patients and in industry on drug development. He joined the FDA in 2012 as Deputy Center Director for CBER and became Center Director in January 2016.

FDA INVITED

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

About the Speakers

Timothy Martin, PhD – Lieutenant Martin, PhD, USPHS, is a Regulatory Officer stationed at the FDA, where for the past five years he has conducted technical engineering review and GMP compliance of biological products and medical devices in a variety of marketing applications and supplements. Prior to joining the FDA, Dr. Martin held positions in academia (2010 – 2015), developing novel gene therapies and pharmaceutical industry (2005 – 2010) as a process engineer. Dr. Martin served as a Combat Engineer in the Marine Corps Reserves for six years and deployed for two tours (2002; 2006) for the Iraq war.

Melissa J. Mendoza, JD – Ms. Mendoza is the Deputy Director of the Office of Compliance and Biologics Quality (OCBQ) in the Center for Biologics Evaluation and Research at the U.S. Food and Drug Administration. OCBQ is responsible for ensuring the quality of products regulated by CBER over their entire lifecycle, from pre-market review and inspection to post-market review, surveillance, inspection, outreach, and compliance. Before joining CBER, she served for eight years in FDA's Office of the Chief Counsel where she was an Associate Chief Counsel for Enforcement.

Els Poff, BS, MS – Ms. Poff is the Executive Director of the Data Integrity Center of Excellence for Merck & Co., Inc. She is responsible for overseeing the execution of all quality and GMP compliance remediation and sustainment activities related to data integrity for the Merck manufacturing sites and external partners network. Ms. Poff graduated from the Industrial College of Brussels, Brussels, Belgium, where she earned a BS in Industrial Engineering and a Master of Engineering degree in Mechanical & Industrial Engineering.

Zhihao Peter Qiu, PhD – Dr. Qiu is an Acting Director in the Division of Biotechnology Manufacturing, Office of Pharmaceutical Manufacturing Assessment, CDER, FDA. The Division oversees the scientific assessment and quality evaluation of the manufacturing and control and facilities for Biologic License Applications (BLA). The Division is also responsible for conducting pre-license inspections for CDER regulated BLAs. Prior to his current position, he was an acting Division Director in the Division of Microbiology Assessment and a Branch Chief in the Division of Inspectional Assessment, Office of Process and Facilities, CDER.

Joseph T. Varghese, BS, MBA – Mr. Varghese is the Head of Global Quality GxP Data Integrity at Bristol-Myers Squibb. He has over 18 years of industry experience. Prior to joining BMS, Mr. Varghese worked at Teva Pharmaceuticals, Merck, and Schering-Plough, where he had extensive experience in compliance, data integrity, computer systems validation, quality systems development, change management and documentation.

Shane A. Yount, BA – Mr. Yount is a nationally recognized thought leader, author, and President of Competitive Solutions, Inc. (CSI), an international Business Transformation consulting firm which pioneered the acclaimed organizational development system known as Process Based Leadership®. Since 1991 he has led the offices of CSI in becoming one of the nation's most recognized Business Transformation consulting firms, personally working with such organizations as Michelin, Genentech, Pfizer, Lockheed Martin, the Department of Defense, and many others.

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

Agenda

Monday, August 9, 2021
Morning Session: Moderator – Gary Bird, PhD

8:00 – 9:00	Registration	
9:00 – 9:10	Welcome	
9:10 – 9:15	Icebreaker	
9:15 – 9:45	**Keynote: Milestones in the History of the GMP Regulations**	David Chesney
9:45 – 10:15	**Center Update: CBER**	Peter Marks, MD, PhD, FDA, CBER – invited
10:15 – 10:35	Break*	
10:35 – 11:05	**Center Update: CDER**	FDA, CDER – invited
11:05 – 11:35	**Center Update: ORA**	FDA, ORA – invited
11:35 – 12:15	**General Topics of ORA Interest**	Alonza Cruse, FDA, ORA – invited
12:15 – 12:35	**Question and Answer Session**	Morning Speakers
12:35 – 1:50	Lunch*	

Afternoon Workshops

1:50 – 3:20	**Workshop 1: The Unintended Consequences of Noncompliance of Your Domestic and Foreign CMOs**	Industry: Armando Cortes Industry: Michael Kinley CDMO: To be determined FDA: ORA – invited

Workshop 2: Case Study: Decision-Making and Documentation

Robert Darius
Douglas Farquhar
Raymond Bonner

FDA has issued numerous Warning Letters to manufacturers faulting them for inadequate investigations, be they into impurities, complaints, stability failures, or deviations. Indeed, FDA criticisms directed at how investigations are conducted and documented have risen to a level nearly as predominant as data integrity issues were five or six years ago. Similarly, FDA's inspection reports frequently cite a company's failure to document decisions about whether to conduct recalls, about whether to file Field Alert Reports or Adverse Event Reports, and about whether a manufacturing change needs to be reported to FDA prior to implementation. This workshop will concentrate on different techniques to guide investigations and other deliberative processes (Kepner-Trego, 5Ys, Fishbone Analysis, Deming, etc.) and provide a toolkit to Quality professionals that they can consider using to guide documentation of investigations and the decision-making process.

Agenda

Workshop 3: CGMP for Cell and Gene Therapy Products
Cell and gene therapy manufacturing processes and facilities are often complex. In this workshop, we will discuss how CGMP may be applied to control product quality in a variety of manufacturing scenarios, including facility controls, aseptic process validation, process equipment, contract manufacturing, container closure systems, and multiproduct facilities.

Timothy Martin, PhD, FDA, CBER, DMPQ

Workshop 4: Case Study: Operationalizing Data Integrity
Attendees will review real-world case studies to understand and discuss best practices for:

- Detecting emerging risks and challenges to a data integrity program
- Tackling risk-based remediation and prioritization strategies
- Moving from a "DI program" toward a sustainable data management approach

John Avellanet
Els Poff
Joseph Varghese

3:20 – 3:40	Break*	
3:40 – 5:10	**Workshops Session 2 - the above workshops will be repeated**	
6:00 – 7:30	Networking Reception*	

Tuesday, August 10, 2021
Morning Session: Moderator – Brian L. Bishop, PhD

8:30 – 8:35	Icebreaker	
8:35 – 9:05	**What's the Impact – Proactive Compliance from a Legal Perspective**	Raymond Bonner Douglas Farquhar
9:05 – 9:35	**Continuous Manufacturing** *(Case Study of Implementation)*	Gary Dodakian
9:35 – 10:05	**The Emerging Paradigm of Integration of Regulatory Application Review and Inspection**	Zhihao Peter Qiu, PhD, FDA, CDER
10:05 – 10:25	Break*	
10:25 – 11:05	**Quality Metrics and Quality Maturity – The Journey Forward**	Jennifer Maguire, PhD, FDA, CDER
11:05 – 11:45	**The Future of Artificial Intelligence/Machine Learning**	To be determined
11:45 – 12:20	**Proactive Compliance (Process Based Leadership)**	Shane Yount
12:20 – 12:45	**Question and Answer Session**	Morning Speakers
12:45 – 2:00	Lunch*	

Agenda

Afternoon Workshops

2:00 – 3:30

Workshop 1: New Manufacturing Facility Modalities to Meet the Need for Flexible and Rapidly Deployable Capacities

Maik Jornitz
To be determined

With the need for flexible and rapidly deployable manufacturing capacities to meet current new therapy demands and continuous bioprocess requirements, innovative and much more outside the box facility designs are required. Traditional cleanroom build-outs and facility construction do not meet the aggressive manufacturing timelines, do not fulfill the reliability needs for delivery and cost budgets and often are too expensive to make the upfront investments. New facility modalities and designs allow the delivery of cleanroom infrastructures or entire turnkey facilities between 6-12 months. In addition, autonomous cleanroom infrastructures allow scalability of the processing footprint in a staggered approach without interrupting existing processes. Since these structures are mobile, capacities can be regionally shifted. The workshop will discuss the needs of the industry and regulators for new facility designs and modalities. It will review the strengths and weaknesses of the traditional solutions versus the new solutions.

Workshop 2: A Coach Approach to Leadership – Keys to a Thriving Organization

Steve Greer

This workshop provides an overview of what a coach approach to leadership consists of, why it is important and the key skills every leader needs to develop to win in today's organizations. The workshop includes interactive exercises to practice the concepts discussed. If you want to thrive as a leader, you don't want to miss this workshop!

Workshop 3: Case Studies: Simple Approaches for Deviation Investigations and Corrective Actions

David Doleski
Robert Darius
Jeffrey Carter

This workshop will explore several simple ways to assess root cause and CAPAs with tools you can take back to your sites through case studies and sharing best practices. The key elements necessary for successful investigations will be practiced in order to share what a good investigation looks like. This exercise will be done from the viewpoints of pharma industry and regulatory oversight and assessment of your investigations.

Workshop 4: Case Study: Track and Trace – an Industry Discussion on Implementation

To be determined
FDA, ORA – invited

3:30 – 3:50 Break*

3:50 – 5:20 **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

Wednesday, August 11, 2021
Morning Session: Moderator – Steve Greer

7:30 – 8:20	**Breakfast with Investigators**	FDA – invited
8:30 – 9:00	**A Coach Approach to Leadership – Attracting, Retaining, and Leading a High Performing Organization**	Steve Greer
9:00 – 9:30	**Creating and Maintaining a Quality Culture in Your Organization** – How do you persuade everyone to move toward the same quality goals? – How do you persuade everyone to recognize those goals are for the good of the organization? – Goal-based orientation and recognizing that everything performs a certain way	To be determined
9:30 – 10:00	**Interacting with FDA – Sharing Good and Bad News**	Thomas Cosgrove
10:00 – 10:15	**Question and Answer Session**	Morning Speakers
10:15 – 10:35	*Break	
10:35 – 11:05	**Update on PIC/S Activities**	FDA, ORA – invited
11:05 – 11:30	**CDER Compliance Update**	FDA, CDER – invited
11:30 – 11:55	**CBER Compliance Update**	Melissa Mendoza, FDA, CBER – invited
11:55 – 12:20	**Office of Enforcement Update**	Scott MacIntire, FDA, ORA, OEIO – invited
12:20 – 1:00	**Moderated FDA Panel with Audience Interaction**	FDA Speakers
1:00	Closing	
1:00 – 1:45	*Lunch on your own	
1:45 – 3:45	*Bonus 25th Anniversary Post-Conference Workshop for All Attendees:* **Auditing for Data Integrity like an FDA Investigator** **Click here for details on this workshop**	John Avellanet

*Denotes non-educational activity

Sign up when you register for the main conference

Continuing Education

This conference qualifies for 17.0 hours of continuing education credit. The Data Integrity workshop qualifies for 2.0 hours of continuing education credit.

Registration

25th Annual GMP By The Sea

Fees

	Industry	U.S. Gov't & Press
EARLY DISCOUNT: Payment Received By May 7, 2021	❑ $2595	❑ $1895
Payment Received After May 7, 2021	❑ $2795	❑ $1895

Includes conference materials, continental breakfasts, breaks, lunches, networking reception, and evening social per agenda plus **BONUS POST-CONFERENCE WORKSHOP**

Cancellation Policy: 30 days or more for a full refund less $250 USD 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.

CLICK HERE TO REGISTER ON OUR SECURE SERVER

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
$245 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 23, 2021, 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: **https://www.hyatt.com/en-US/group-booking/CHESA/G-PHMA**
Copy and paste the URL in your browser to make hotel reservations online or call (410) 901-1234.

The conference area in the hotel is large enough to allow for proper social distancing, and the hotel has agreed to disinfect everything in the meeting rooms and dining areas daily. Visit Hyatt.com for more details on the hotel.

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

CLICK HERE TO REGISTER ON OUR SECURE SERVER