The top GMP conference in the U.S.!

Adapting GMPs to New Technologies/the Future – The Winds of Change

24TH ANNUAL GMP BY THE SEA

AUGUST 12 – 14, 2019 | CAMBRIDGE, MARYLAND

Featuring our popular Maryland Eastern Shore Dinner evening!

Conference produced by

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About the Conference

Almost 60 years of modern GMPs and we still do not have a worldwide consensus that describes all the expectations for GMPs. While the new regulations and requirements may be similar in many of their elements, the "devil is in the details" and oftentimes, the details differ. Ultimately, it is up to each company to understand each of the requirements and create its own interpretation. The challenge: as soon as one new regulation or guidance appears, another follows, and companies oftentimes do not have time to interpret, evaluate conflicts within their existing systems, or implement.

Our theme this year is "***Adapting GMPs to New Technologies/the Future – The Winds of Change.***" This year, we have 13 FDA speakers (all confirmed) representing CDER, CBER, ORA, and more, as well as top industry experts. These speakers will focus on the issues in the changing world of GMP compliance which affect you and your company. For example,

- **Veronica Cruz**, PhD, Vice President for Global Quality at Romark, will be our opening session plenary speaker and will discuss the disconnect between the understanding of quality on the manufacturing floor versus the understanding of quality in the "C" suite. Why do so many executives believe that quality in their company is actually better than it is?
- **Monica Cahilly**, President of Green Mountain Quality Assurance, LLC, the consultant who ***trains the FDA on Data Integrity***, will present a plenary session talk on "**Auditing with an Eye on Integrity**" and a workshop on "**Data Integrity Audit Methods**."
- A high level industry panel will focus on the directions of GMPs and potential requirements for the next generation of novel drug products.
- **Alonza Cruse**, Director, ORA's Office of Pharmaceutical Quality Operations, will discuss the hot topics in ORA focusing on the New Inspection Protocol Program, which will affect all companies, and inspection preparedness in the immediate future.
- **Captain Sean Boyd**, the Deputy Director for Regulatory Affairs in CDRH's Office of Compliance, will bring **CDRH's perspective** on the new device Quality System Regulations which frequently impact the pharmaceutical world.
- **Mark Davison**, author and well-known industry leader, will discuss the next looming issues related to "Track and Trace: Impact on Supply Chain and GDPs (Good Distribution Practices)." While not at the forefront of discussion these days, these looming requirements require not just a simple barcode, but rather a complete system of standards to confirm compliance.
- **Celia Witten**, MD, PhD, Deputy Director, CBER, has agreed to provide an update on the activities occurring within CBER in her Center update.

This year's workshop format at GMP By The Sea will be the highlight as always. Eight sessions provide an opportunity to speak with FDA experts and industry colleagues informally. These are repeated, so you can attend two of the four offered each afternoon.

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 featuring crabs and other non-seafood entrees.

GMP By the Sea has always provided 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.

About the Conference

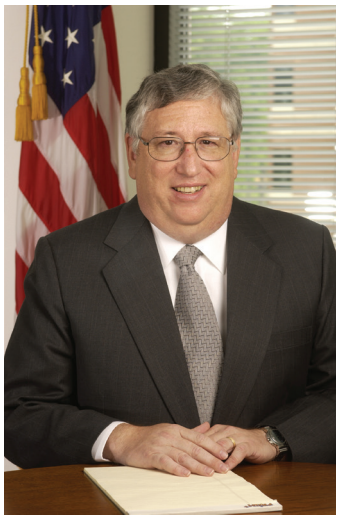
Who Should Attend?

- 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.

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

In Memoriam: Mark Elengold



Our conference this year is dedicated to our great friend – Mark Elengold. After fighting failing health for the last several years, Mark Elengold passed on February 1, 2019. Mark was more than conference Chairman for GMP By The Sea for the last 12 years; he was a friend to every attendee of the event, regaling us with his never ending supply of FDA stories which were all the more remarkable because they were true. His career lasted for 34 years at the Food and Drug Administration in ORA, CDER, and CBER. At every stop in his remarkable career he made friends with the most influential and powerful persons including FDA, Industry, and international Regulatory Authorities. His career was a reflection of the events and milestones that shaped the way FDA regulates products today. From his early career years in the field, to helping create the world of Generic Drugs, to transition the old Product License Application to today's Biologics License Application, to working to establish Team Biologics as Deputy Director of CBER, Mark was a walking history of the FDA. Complex discussions to Mark were nothing more than a series of very simple decisions. Even after leaving FDA, Mark retained a fierce devotion to FDA's core mission of consumer protection. He would tell it "as it is." His insight was remarkable and his wit, though often acerbic, was always pointed and honest.

What most people don't know is that Mark and his wife Linda were avid cruisers and had spent cumulatively more than two years cruising the seas of the world. We will miss Mark, and we appreciate his service to FDA and to GMP By The Sea these many years. Most of all, we will miss our friend.

About the Speakers

Jennifer Ahearn, BS – Mrs. Ahearn specializes in pharmaceutical regulatory compliance and is the Director, Regulatory and Compliance, Pharmaceutical and Medical Devices for Engineering Systems, Inc. Prior to this, she held numerous roles within the FDA including bench chemist, domestic and international investigator, technical liaison for FDA's Office of Criminal Investigations, and member of FDA's National Training Cadre. Mrs. Ahearn has assisted pharmaceutical companies preparing for FDA inspections, as well as responding to FDA 483 observations after an inspection, and worked to resolve technical and FDA compliance issues for virtually all pharmaceutical dosage forms.

FDA

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 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.

FDA

Ashley Boam, BSE, MSBE – Ms. Boam currently serves as Director of the Office of Policy for Pharmaceutical Quality (OPPQ) in the Office of Pharmaceutical Quality (OPQ) in the Center for Drug Evaluation and Research (CDER). OPPQ is responsible for developing and clearly communicating science- and risk-based policies and standards related to drug product quality, including application review and inspection. Prior to joining CDER in 2013, Ms. Boam spent nearly 20 years in the Office of Device Evaluation (ODE) in FDA's Center for Devices and Radiological Health (CDRH), serving as a scientific reviewer, a Branch Chief in the Division of Cardiology Devices, and finally as Associate Director for Regulations and Guidance for ODE.

FDA

Sean M. Boyd, MPH – Captain Boyd serves as the Deputy Director for Regulatory Affairs in the Office of Compliance at FDA's Center for Devices and Radiological Health (CDRH). He is responsible for managing the Center's quality initiatives, as well as regulatory compliance and enforcement programs for the medical device industry. Captain Boyd's experience includes that of a regulatory researcher and engineering analyst, compliance reviewer, and manager of several organizations within FDA. He has been responsible for all aspects of medical device premarket, postmarket and compliance activities and, prior to joining the Office of Compliance in 2015, led and transformed many aspects of CDRH's electronic product radiation control program.

spotlight SPEAKER

Monica Cahilly, BA, MS – Ms. Cahilly is President/Consultant, Green Mountain Quality Assurance, LLC. Among other things, she provides ongoing training on the topic of Data Integrity Investigations to FDA as well as to WHO, MHRA, EMA, PIC/S, PMDA, TGA, and others. She has been consulting for 27 years, with specialized interest in Data Integrity Assurance.

About the Speakers

Andrew Chang, PhD – Dr. Chang has more than 20 years of experience in the development, regulation and quality of biologics and pharmaceuticals. At his current capacity as a Vice President, Quality and Regulatory Compliance, Quality Intelligence and Inspection, Novo Nordisk Inc., he is responsible for external affairs, providing strategic advice and solutions for quality and regulatory related issues, and expert support to inspection preparation. Prior to Novo Nordisk, Dr. Chang served more than 11 years at USFDA, most recently as an Associate Director for Policy and Regulation, Acting Deputy Director and Senior Regulatory Scientist in the Division of Hematology, Center for Biologics Evaluation and Research (CBER).

Alonza Cruse, BS – Mr. Cruse is Director, Pharmaceutical Quality Program within the FDA Office of Regulatory Affairs. His 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, Mr. Cruse was the Director, FDA's Los Angeles District Office. Mr. Cruse first joined ORA in 1983 as a microbiologist.

Veronica Cruz, PhD – Dr. Cruz is Vice President, Global Quality, for Romark, LC. Some of her significant achievements include leading the development and successful execution of a consent decree. In 2008, she received the "Women Who Rule" recognition by Caribbean Business and in 2016 was recognized by PRMA as "Industrial Woman of the Year".

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.

Mark Davison, BSc (Hons) – Mr. Davison is Vice-President, International Business, at Rfxcel Corporation. He has spent the last 13 years working on global health security issues such as serialization, supply chain security, and their impacts on GxP and industrial processes. Mr. Davison is an expert in traceability legislation, including the Drug Supply Chain Security Act, EU Falsified Medicines Directive and emerging laws in Argentina, Brazil, China, India, Korea, Russia, etc., and is the author of "Pharmaceutical Anti-Counterfeiting" (Wiley, 2011).

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.

Joyce L. Frey-Vasconcells, PhD – Dr. Frey-Vasoncells is Regulatory Expert, Frey-Vasconcells Consulting, LLC. She is considered one of the foremost regulatory experts regarding cell therapies, combination products, gene therapies, tumor vaccines, and tissues and brings extensive regulatory expertise and experience for this unique group of products. Prior to starting Frey-Vasconcells Consulting, Dr. Frey-Vasconcells served six years as a regulatory consultant for Pharmanet. Prior to joining Pharmanet, she served more than 12 years at the FDA. At FDA, Dr. Frey-Vasconcells was the Deputy Director, Office of Cellular, Tissue, and Gene Therapies (OCTGT) with the Center for Biologics Evaluation and Research (CBER).

Milind Ganjawala, BS, MS, MBA – Mr. Ganjawala serves as the Acting Division Director of the Division of Drug Quality 2 (DDQ2), Office of Manufacturing and Product Quality (OMPQ), Office of Compliance (OC), Center for Drug Evaluation and Research (CDER), FDA. Prior to coming to FDA, Mr. Ganjawala spent more than 20 years in quality management positions within world class pharmaceutical and biotech companies.

About the Speakers

Steve Greer, BS – Mr. Greer is the External Engagement Leader in Corporate QA for Procter & Gamble responsible for building collaborative relationships with boards of health and industry associations. At P&G, he has held leadership roles in manufacturing and quality assurance across the drug, cosmetic and home care sectors. He is co-chair of the Personal Care Products Council QA Committee and serves on the Quality Metrics Core Team of ISPE. Mr. Greer helps lead and is a popular speaker at numerous conferences on quality metrics, quality culture and improving human performance.

Sau (Larry) Lee, PhD – Dr. Lee joined FDA in 2005 and has served as regulatory scientist, CMC team leaders, Associate Director for Science, and Deputy Office Director. He is the Director for Office of Testing and Research within OPQ, and he is also a chair for OPQ led Emerging Technology Program and led a multi-disciplinary team with representation from OPQ, OC and ORA to support the development, implementation and regulatory evaluation of novel technologies for pharmaceutical applications. In 2016, Dr. Lee was promoted to the Senior Biomedical Research Service (SBRS) because of his regulatory and scientific contributions to manufacturing science, complex drug substances and products, and emerging pharmaceutical technologies.

Michael Levy, JD – Mr. Levy is the Deputy Director for Policy and Analysis in the Office of Compliance at CDER. He joined FDA in 2000 as an Associate Chief Counsel for Enforcement in the Office of the Chief Counsel. In 2006, he joined CDER Office of Compliance as the Director of the Division of New Drugs and Labeling Compliance. Mr. Levy graduated cum laude from Duke University School of Law in 1997 and magna cum laude from Amherst College in 1993.

Philip Lin Huang, MD, MBA – Dr. Huang is a physician executive with 20 years in biopharma and six years in clinical practice. He is currently Regional Quality Head, North America at Sanofi. Dr. Huang has expertise and has worked in clinical R&D, regulatory, medical affairs, GxP quality and business development for novel therapies, vaccines, and biosimilars.

John M. 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.

Scott J. MacIntire, BS – Since November of 2014, Mr. MacIntire has been the Director of the Division of Enforcement/Office of Enforcement and Import Operations at FDA's Office of Regulatory Affairs (ORA), where he works closely with FDA centers to include the Center for Drug Evaluation and Research, Center for Biologics and Office of Chief Counsel in determining 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. Prior to his current position, Mr. MacIntire was Director of the Chicago District Office from 2004 to 2014.

Mark Matis, BA – Mr. Matis, Principal Consultant, at PAREXEL Consulting, draws on 20 years of diverse experience to assist companies in regulatory strategy, development, and compliance efforts. Prior to joining PAREXEL, he was a Manager of Computer System Validation at a medical compressed gas company. Previous to that he was a Senior Vice President of Operations of a pharmaceutical training software development company, Director of Quality at an environment analytical laboratory, and Analytical Chemist for commercial environmental analytical testing laboratories.

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About the Speakers

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.

Ellen F. Morrison, BA – Ms. Morrison is the Assistant Commissioner for Medical Products and Tobacco Operations (ACMPTO) in the Office of Regulatory Affairs (ORA) at the Food and Drug Administration (FDA) leading a team that serves as focal point for coordination and management of ORA's medical product and tobacco field activities. 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 federal, state, local, and international agencies, becoming the first Director of the Office of Crisis Management in 2003. She returned to ORA first as acting in 2012 and then officially in 2013, as the Assistant Commissioner for Operations. In 2017, she took on the role of Assistant Commissioner for Medical Products and Tobacco Operations for ORA.

Theresa Mullin, PhD – Dr. Mullin is Associate Director for Strategic Initiatives, CDER, FDA, where she serves as principal advisor on strategy, leads FDA Patient Focused Drug Development, co-leads the New Inspection Protocol Project, and heads the FDA delegation to ICH. She led FDA negotiations in 2017 and the previous three cycles reauthorizing PDUFA, now providing $1B in annual funding. She received the SES Presidential Rank Award for Distinguished Service in 2011, Presidential Rank Award for Meritorious Service in 2006, and the FDLI Distinguished Service and Leadership Award in 2017.

Zhihao Peter Qiu, PhD – Dr. Qiu is a Branch Chief in the Division of Inspectional Assessment, Office of Process and Facilities, CDER, FDA. The Division oversees the scientific review, pre-approval inspection, and quality evaluation of the manufacturing process and facilities for INDs, NDAs, ANDAs, BLAs, and supplements. Prior to his current position, he was a Branch Chief in the Biotech Manufacturing Assessment Branch in the Office of Compliance in CDER, where he managed the microbiology review and pre-license inspection program for CDER's Biologics License Applications.

Kim Trautman, MS – Ms. Trautman is the Executive Vice President, Medical Device International Services at NSF International. She has a 30+ year background in medical devices and in-vitro diagnostics and is a Recognized International Expert in global medical device regulations. Ms. Trautman was with the FDA Center for Devices and Radiological Health (CDRH), where she wrote and harmonized the US FDA Quality System Regulation 21 CFR § 820 and was on the international authoring group of ISO 13485. She has worked with Regulatory Agencies around the globe and is a 20-year veteran of the Global Harmonization Tasks Force (GHTF) and foundational member of the International Medical Device Regulators Forum (IMDRF).

Peter K. 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 IND and BLA submissions, and participation in FDA inspections and GMP audits. Prior to his position at Coherus, Dr. Watler held positions at Hyde Engineering + Consulting, Inc, Vaxgen, Amgen and Allelix.

Celia M. Witten, PhD, MD – Dr. Witten is the Deputy Director of the Center for Biologics Evaluation and Research at the Food and Drug Administration (FDA/CBER). Between 2005 and 2016 she served as the Director of the Office of Cellular, Tissue and Gene Therapy at the FDA/CBER. Between 1996 and 2005 she served as Director of the Division of General, Restorative, and Neurological Devices in the Office of Device Evaluation in the Center for Devices and Radiological Health (CDRH). Previous to FDA, she worked for over 10 years as a practicing physician at the National Rehabilitation Hospital (NRH) in Washington, D.C.

Agenda

THEME:
Adapting GMPs to New Technologies/the Future – The Winds of Change

Monday, August 12, 2019
Morning Session: Moderator – Gary Bird, PhD

8:00 – 9:00	Registration	
9:00 – 9:10	Welcome	
9:10 – 10:00	**Keynote: The Two Sides of Quality – C Suite vs. Manufacturing Floor**	Veronica Cruz, PhD
10:00 – 10:30	**Center Update: ORA**	Ellen Morrison, ORA
10:30 – 10:50	Break*	
10:50 – 11:20	**Center Update: CDER**	Theresa Mullin, PhD, CDER
11:20 – 11:50	**Center Update: CBER**	Celia Witten, MD, PhD, CBER
11:50 – 12:25	**Question and Answer Session**	Morning Speakers
12:25 – 1:40	Lunch*	

Afternoon Workshops

1:40 – 3:10	**Workshop 1: Status of and Work In Progress Guidances, Where is FDA Going?**	Ashley Boam, CDER
	Industry Side of Implementing New Guidances	Industry – Andrew Chang
	Workshop 2: Audit Trail Reviews: A Pragmatic Process to Go from Guidance to SOP	Mark Matis

A look at the who, what, when, where and why aspects of conducting timely and robust audit trail reviews as part of the data review and approval process and working with the system SME and IT to determine the how to access this information for review ensuring data integrity throughout the data lifecycle.

Workshop 3: Future of Manufacturing: Next Generation GMPs – Continuous Manufacturing, Personalized Medicines — Sau (Larry) Lee, PhD, CDER

Those not moving forward will be left behind.Those who adapt and innovate will lead our industry forward; the rest will either follow or fade away. This is not only true for pharmaceutical manufacturing but also for the adaptation of GMPs to these new technologies. Come learn from the FDA about exciting developments in innovative technologies at the forefront of our industry. Learn how the regulatory and manufacturing landscape are evolving to enable this promising new future. Participate in the dialog with the FDA and help shape the possibilities.

Workshop 4: Pros and Cons of Self-Disclosure — Douglas Farquhar

Violations of cGMP uncovered by FDA can lead to serious enforcement consequences: Warning Letters, seizures, Official-Action-Indicated status that can block product approval or clearance, import alerts, criminal investigations. When you uncover serious violations of cGMP, should you self-disclose them to FDA? When are you required to? This workshop explores the considerations driving the decision whether to disclose, decisions made under tight time deadlines and under serious stress.

Agenda

3:10 – 3:30	Break*	
3:30 – 5:00	**Workshops Repeated - the above workshops will be repeated**	
5:30 – 7:30	**Networking Reception***	

Tuesday, August 13, 2019
Morning Session: Moderator – John Hyde

8:30 – 9:00	**CDRH Directions for GMPs, A New QSR (Quality System Regulations)**	Captain Sean Boyd, CDRH
9:00 – 9:30	**Track and Trace: Impact on Supply Chain and GDPs (Good Distribution Practices)**	Mark Davison
9:30 – 10:00	**Quality Metrics: The Future of Quality Metrics (QM) to Actually Influence Decisions/Compliance (Case Study)**	Steve Greer
10:00 – 10:20	Break*	
10:20 – 10:50	**Adopting External Standards to Build a QMS (ISO, ASME)**	Kimberly Trautman
10:50 – 11:20	**Applying Common GMPs to Unique Technologies: Gene Therapy/3D Printing/Stem Cell**	Joyce Frey-Vasconells, PhD
11:20 – 12:20	**An Industry Discussion Panel on the Globalization of GMPs: Challenges, Issues and Directions**	Kimberly Trautman Robert Darius John Hyde Peter Watler, PhD
12:20 – 12:45	**Question and Answer Session**	Morning Speakers
12:45 – 2:00	Lunch*	

Afternoon Workshops

2:00 – 3:30 **Workshop 1: Data Integrity Audit Methods** Monica Cahilly

This 90-minute workshop will discuss advanced techniques for auditing laboratory and production records. We will follow real-world case studies where data integrity breaches were identified in both paper and electronic records, and demonstrate the techniques used by the investigator to build the case.

Workshop 2: Best Practices in Change Management Jennifer Ahearn

Change control monitors all types of changes which can influence process reliability or product quality. The workshop will cover creating an effective change control procedure, monitoring the effectiveness of changes, challenges associated with a change control program and FDA 483/Warning Letter examples relating to change control.

Workshop 3: Virtual and Small Company Responsibilities – Issues on Outsourcing Peter Watler, PhD, John Hyde

Workshop 4: Best Practices for Handling Complaints, Philip Lin Huang

Agenda

Submissions and Recalls — Milind Ganjawala, CDER

Session devoted to a discussion between Industry and FDA representatives on handling of Complaints, related Regulatory Submissions, and Recalls where best practices are shared and discussed that result in rapid and transparent communications. Challenges for dealing with Recalls will be discussed sharing case studies and best practices.

3:30 – 3:50	Break*	
3:50 – 5:20	**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 14, 2019
Morning Session: Moderator – Diane Alexander, CBER

8:30 – 9:00	**Transitioning Inspections of Protein Products from Select NDAs to BLAs**	Zhihao Peter Qiu, PhD, CDER
9:00 – 9:40	**Auditing with an Eye on Integrity**	Monica Cahilly
9:40 – 10:10	**Hot Topics with a Focus on the New Inspection Protocol Program**	Alonza Cruse, ORA
10:10 – 10:40	**CDER Compliance Update**	Michael Levy, CDER
10:40 – 11:00	*Break	
11:00 – 11:30	**CBER Compliance Update**	Melissa Mendoza, CBER
11:30 – 12:00	**Office of Enforcement Update**	Scott MacIntire, OEIO, ORA
12:00 – 12:45	**Ask FDA Q&A Session**	FDA Speakers

*Denotes non-educational activity

Continuing Education

This conference qualifies for 16.0 hours of continuing education credit.

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 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 https://chesapeakebay.regency.hyatt.com/en/hotel/our-hotel/map-and-directions.html

Registration

24th Annual GMP By The Sea

Fees

	Industry	U.S. Gov't & Press
EARLY DISCOUNT: Payment Received By May 3, 2019	❑ $2395	❑ $1495
Payment Received After May 3, 2019	❑ $2595	❑ $1495

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

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.

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Payment

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

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

Hotel

Hyatt Regency Chesapeake Bay Hotel
100 Heron Blvd
Cambridge, MD 21613
(410) 901-1234
$235 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 26, 2019, 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-GMPP**
Copy and paste the URL in your browser to make hotel reservations online or call (410) 901-1234.

For additional information, contact Pharma Conference Inc:
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