

# The top GMP conference in the U.S.!



Navigating the changing world of GMPs

## 23<sup>RD</sup> ANNUAL GMP BY THE SEA

AUGUST 27 - 29, 2018 | CAMBRIDGE, MARYLAND

*Featuring our popular  
Maryland Eastern  
Shore Dinner evening!*



Conference produced by



*The top producer of premier  
pharmaceutical conferences  
for the past 23 years*



# About the Conference

There is no doubt that the pharmaceutical industry is facing its most difficult time in years trying to meet compliance standards being promulgated worldwide by regulatory authorities. Almost every company has the challenge of meeting regulatory standards for compliance in their manufacturing organizations because many of these same companies, long thought to be compliant and financially viable, are now learning what the regulators really expect of them. Quality groups are facing the greatest challenges they have ever faced. It's difficult for even the best organization to keep up with the challenges facing them worldwide from the ever-more-present regulatory authorities. All the while, politicians and third-party payers are insisting companies reduce their costs.

Seldom in the industry's history have things changed as rapidly as they have recently. One thing that is NOT changing is that **GMP By The Sea** remains the premier, must-attend conference for anyone in quality, regulatory affairs, manufacturing, or related positions who wants to navigate the current regulatory environment. The conference this year will have speakers who will focus on some of the most important issues in the changing world of GMP compliance; issues which affect you and your company. For example:

- Mr. David Cockburn, recently retired Head of the Manufacturing and Quality Compliance Service in the European Medicines Agency (EMA), will present an up-to-date discussion on "GMP and a Post-Brexit Europe – What Now?".
- Mr. Alonza Cruse, Director, ORA's Office of Pharmaceutical Quality Operations (OPQO), will discuss the recently completed inspection pilot program that may be in everyone's future.
- Dr. Peter Marks, Director of the Center for Biologics Evaluation and Research, will discuss, among other things, the recently announced initiative by CBER to adopt external standards for key areas of manufacturing processes and controls.

As usual, plenary sessions will include FDA keynotes from CBER and CDER's Office of Compliance, ORA and the Director of the Division of Enforcement in ORA.

This year's workshop format will be the highlight it always is. Industry experts are clamoring to lead these well-recognized events. Eight sessions provide an opportunity to speak with FDA experts and industry colleagues informally. 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 crab dinner (and non-seafood).

**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 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 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

Register online at [www.pharmaconference.com](http://www.pharmaconference.com)



# About the Speakers



**Sandra Ahern, MSc, MBA** – Ms. Ahern is the Senior Director and Site Quality Head of Framingham Biosurgery at Sanofi. She has over 30 years of experience in Quality, the last 20 years spent at Sanofi, in areas covering Biosurgery, Clinical Supply, Corporate Auditing, Biologics, Cell Therapies, and Pharmaceuticals in the US and EU. Prior to her current position, Ms. Ahern was North American Head of Clinical Supply Quality for Sanofi and responsible for Global Complaints for Clinical Trials.



**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.



**Donald D. Ashley, JD** – As Director of the Office of Compliance for the Center for Drug Evaluation and Research, Mr. Ashley leads the Food and Drug Administration's efforts to protect the American public from unsafe and ineffective drug products by ensuring that companies comply with federal standards for quality and safety. Before joining the FDA, Mr. Ashley served as a prosecutor with the Department of Justice for more than 18 years. Earlier in his career, Mr. Ashley was a senior litigation associate with King & Spalding and served as an Army Captain with the Department of the Army's Office of General Counsel.



**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 different agreed guidances.



**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. This Office also coordinates OPQ's work with international regulatory authorities on quality issues, leads CDER's compendial operations, coordinates CDER's involvement in quality standard-setting organizations, and addresses policy issues related to drug-device combination products. 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.



**David L. Chesney, BS** – Mr. Chesney is the Principal and General Manager for DL Chesney Consulting, LLC. He was formerly the Vice President, Strategic Compliance Services for PAREXEL Consulting. Prior to joining PAREXEL Consulting (then known as KMI) in 1995, he served 23 years with the FDA. Between 1972 and 1988, Mr. Chesney advanced from Investigator to Supervisory Investigator and Director, Investigations Branch, working in the Boston, Seattle and Philadelphia District Offices. In 1991, he was appointed the District Director, FDA San Francisco District Office, where he served until joining PAREXEL. In his time with PAREXEL, Mr. Chesney provided compliance consulting and training services to clients world wide.



**Chrissy J. Cochran, PhD** – Dr. Cochran is the Director of the Office of Bioresearch Monitoring Operations at the FDA and is responsible for working with each of FDA's product centers to establish and manage the Agency's BIMO program. She previously led the Division of Enforcement and Postmarketing Safety in CDER, led the good laboratory practice compliance program in CDRH, monitored clinical trials at a large clinical research organization, and performed laboratory research at the Veteran's Administration.



**David Cockburn, BSc (Hons)** – A Pharmacy graduate, Mr. Cockburn has a grounding in the pharmaceutical industry augmented by roles in the authorities at national and EU level. Industry exposure included Regulatory Affairs at GD Searle and in Production at Glaxo Operations, both in the UK. Mr. Cockburn joined MHRA as a Principal Medicines Inspector and spent 14 years there before moving to the European Medicines Agency for 15 years and becoming Head of Manufacturing and Quality Compliance.



**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.



**Richard J. Davis, BS** – Mr. Davis operates Richard Davis & Associates LLC, providing quality assurance and supply chain services to the international pharmaceutical industry. He was formerly employed by Bristol Myers Squibb and the DuPont Pharmaceutical Company as Senior Vice President for Quality Assurance and Regulatory Compliance. At DuPont he was responsible for worldwide quality assurance and regulatory compliance. Prior to this, Mr. Davis was the Regional Director for the Mid-Atlantic Region of the FDA from 1977 to 1994. He joined the FDA in 1961 and served in a number of positions before his appointment to Regional Food and Drug Director.



# About the Speakers



**Cristina De Simoni Klitgaard, MSc, MBA** – Ms. Klitgaard has 20 years of international experience in the Bio/Pharmaceutical industry and is currently Quality Director and Qualified Person in Biopharm QA at Novo Nordisk A/S. In this position, she and her team ensure oversight and a simplicity-driven governance of quality processes as well as initiate and drive continuous improvements. Main quality processes within her area of expertise are: inspection management, quality management and oversight, and GMP training. In her other previous positions in Janssen-Cilag, Ferring Pharmaceuticals and Novo Nordisk, she had roles in regulatory affairs, product support, and quality assurance for internal and contract manufacturing.



**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.



**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.

Photo  
Not  
Available

**Milind Ganjawala, BS, MS, MBA** – Mr. Ganjawala works for the Food and Drug Administration in the Center for Drug Evaluation and Research (CDER) as the Acting Director of the Division of Drug Quality II (DDQ2) in the Office of Manufacturing Quality (OMQ), Office of Compliance (OC). Prior to coming to FDA, he had more than 20 years experience in quality management positions within world-class pharmaceutical and biotech companies.



**David Glasgow** – Mr. Glasgow is the Deputy Director, Office of Bioresearch Monitoring in the Office of Regulatory Affairs for FDA. He has been with FDA for over 30 years as an investigator, supervisor and manager. Mr. Glasgow started his FDA career in the Los Angeles District in 1987 and has since served in six district offices across the country as well as ORA HQ.



**Scott Goodberlet, BA** – Mr. Goodberlet is the Head of Quality for North America at GlaxoSmithKline with responsibility for the Quality aspects of the supply of pharmaceutical products in the US and Canadian markets. He has over 25 years of experience working in both R&D and manufacturing organizations. Mr. Goodberlet started working for GlaxoSmithKline in 2000 and was responsible for laboratory and quality operations and improvement initiatives at a number of key manufacturing facilities. He then went on to Site Quality Director roles in Europe and the US. Prior to joining GSK, Mr. Goodberlet worked at Fisons Pharmaceuticals in both QC and R&D laboratories.



**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.



**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.





# About the Speakers



**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.



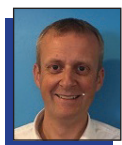
**Melissa J. Mendoza, JD** – Ms. Mendoza is the Deputy Director of the Office of Compliance and Biologics Quality (OCBQ) in the Center for Biologics Evaluation and Research at the U.S. Food and Drug Administration. OCBQ is responsible for ensuring the quality of products regulated by CBER over their 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.



**Charles T. Morton, BS** – Mr. Morton is an Associate Director in Global Security at Merck where he leads supply chain security initiatives to enable the secure and efficient movement of Merck products and materials worldwide. He has over 20 years of combined experience in law enforcement, homeland security, supply chain security, and corporate security management. Mr. Morton is a former Vice President and North America Security Manager at Panalpina and served at the Transportation Security Administration (TSA) as Director of the HAZMAT Threat Assessment Program and is the former TSA Branch Chief for Highway Cargo Security.



**Lisa Robertson, BS, MS** – Ms. Robertson is the Head of Global Quality Risk Management for Sanofi. She is responsible for the deployment of a proactive Quality Risk Management program across critical Sanofi sites. Ms. Robertson started working for Genzyme in 2003 within the medical devices platform with focus on the development of the Design Control and Risk Management programs. Her leadership role progressed into the Biologics area of the organization as the Head of Risk Management for that platform. Prior to joining Sanofi, Ms. Robertson worked for Stryker Corporation and J&J Ortho-McNeil in the areas of Operational Management, Quality Management and Project Management.



**Stig Stovgaard, BSc** – Mr. Stovgaard has 20 years of international experience in the Pharmaceutical industry and is currently Quality Vice President heading up Contract and Local Manufacturing QA at Novo Nordisk A/S. In this position, he and his unit are responsible for Quality Assurance, Quality Oversight and release of products from contract manufacturers globally. In his previous positions in H.Lundbeck and Novo Nordisk, he headed up various departments in Production, Production Support and Quality Assurance both within Bio/Pharmaceuticals and Devices.



**Michael A. Swit, JD** – Mr. Swit has been addressing critical FDA legal and regulatory issues since 1984. Before returning to private practice in late 2017, he served most recently as the chief regulatory and quality lawyer at Illumina, the leading developer of gene sequencing technology. Before Illumina, he was at Duane Morris LLP as a Special Counsel in the firm's FDA Law Group. Before joining Duane Morris in 2012, Mr. Swit served for seven years as a Vice President for The Weinberg Group, a premier FDA regulatory consulting firm headquartered in Washington, D.C.



**Claus Weisemann, PhD** – Dr. Weisemann is the Vice President of Quality Affairs at Luitpold Pharmaceuticals, a Daiichi Sankyo Company, manufacturing generic and specialty generic injectables. He is responsible for all Quality, Quality Control and Regulatory Compliance functions including Clinical Quality Assurance across sites in NY, OH, and PA. Previously, Dr. Weisemann held Quality leadership positions with Alexion, Grifols, Watson, and Bayer where he started his career in Germany in Drug Development and R&D. He has worked with large and small molecules and a variety of dosage forms.



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



**Monday, August 27, 2018**

**Morning Session: Moderator – Mark Elengold, Conference Chairman**

8:00 – 9:00	Registration	
9:00 – 9:10	Welcome	
9:10 – 9:40	<b>GMP and a Post-Brexit Europe – What Now?</b>	David Cockburn
9:40 – 10:10	<b>ORA Update</b>	Alonza Cruse, ORA
10:10 – 10:40	<b>Records in Advance or in Lieu of Inspection: An Update on Food &amp; Drug Administration Safety Innovation Act (FDASIA) 706 Implementation</b>	Alonza Cruse, ORA
10:40 – 11:00	Break*	
11:00 – 11:30	<b>CBER Update</b>	Peter Marks, MD, PhD, CBER
11:30 – 12:00	<b>CDER Update</b>	Ashley Boam, CDER
12:00 – 12:20	<b>Question and Answer Session</b>	Morning Speakers
12:20 – 1:35	Lunch*	

## Afternoon Workshops

1:35 – 3:05	<b>Workshop 1: Creating an In-House Data Integrity System</b>	Claus Weisemann, PhD
-------------	---	----------------------

Presentation and discussion will provide practical considerations by pharma management for developing a system/program to help assure data integrity and prevent problems. Presentation will not delve into legal and regulatory positions of FDA, but identify and discuss use of tools, practices, procedures, and behaviors that should be used to: educate staff on expected behavior, provide for staff dismissal, discuss routine management activities for detection, internal audit and management controls for detection, investigation and resolution, and design systems to address human factors. Questions to the audience will help stimulate discussion.

<b>Workshop 2: Alignment of cGMP Expectations in a Global Marketplace</b>	Scott Goodberlet John Hyde
1. Leadership	
2. Due Diligence	
3. Integration Process	
4. Standards – Corporate vs. Local	
5. Portfolio Expansion (Mergers & Acquisitions)	

<b>Workshop 3: FDA Perspectives on Test Article and Finished Products for Use in Non-Clinical and Clinical Testing</b>	Chrissy Cochran, PhD, ORA David Glasgow, ORA
--	---

The requirements for the stage of product development for non-clinical or clinical studies can vary depending on the product being tested. At the conclusion of this interactive workshop, participants should be able to select the appropriate stage of product and testing to be completed prior to study initiation.

<b>Workshop 4: Critical Legal Issues Facing GMP Compliance</b>	Michael A. Swit
--	-----------------

This workshop will explore the critical legal issues associated with non-compliance with GMP requirements, with a focus not only on administrative enforcement powers exercisable by FDA, but also more draconian actions involving the Justice Department such as seizure, injunctions (including consent orders), and criminal prosecution.

3:05 – 3:25 Break\*  
 3:25 – 4:55 **Workshops Repeated - the above workshops will be repeated**  
 5:30 – 7:30 **Networking Reception\***

## Tuesday, August 28, 2018

### Morning Session: Moderator – David Doleski

8:30 – 9:00	<b>Alignment of GMP Expectations in a Global Marketplace</b>	John Hyde
9:00 – 9:30	<b>Minimizing Risks Through Supply Chain Security Management</b>	Charles Morton
9:30 – 10:00	<b>Leadership Keys to Success to Improve Human Performance</b>	Steve Greer
10:00 – 10:20	Break*	
10:20 – 11:00	<b>Building a Robust and Sustainable Proactive Quality Risk Management Program</b>	Lisa Robertson Milind Ganjawala, CDER FDA
11:00 – 11:45	<b>Quality Oversight and Enforcement</b>	Cristina De Simoni Klitgaard
11:45 – 12:15	<b>The Responsibility of Companies – Things Companies Shouldn't Have to Ask FDA</b>	Richard Davis
12:15 – 12:45	<b>Question and Answer Session</b>	Morning Speakers
12:45 – 2:00	Lunch*	

### Afternoon Workshops

2:00 – 3:30	<b>Workshop 1: Leadership Keys to Success to Improve Human Performance</b>	Steve Greer John Hyde
-------------	--	--------------------------

Leadership creates and reinforces the culture of quality in an organization. A common cultural challenge is human error which can lead to poor quality, significant costs, customer service outages, and significant regulatory risk. The keys to improving human performance lie in changing our approach to leadership and creating a strong quality culture.

This session uses case studies from the personal care industry where a site reduced human error by over 50% and achieved significant improvement across all business KPIs. Learn the five leadership keys to success for improving human performance and become a change agent in your organization.

#### **Workshop 2: Best Practices in Responding to 483 Observations with Focus on Senior Management Roles**

Gary Bird, PhD

The observations on the 483s are common. The accusations on the Warning letters are critical. Companies just don't seem to understand how FDA wants companies to respond to observations. Gone are the days that simple SOP changes and "training" are suitable (if they ever were suitable) responses for an observation. Now FDA is clearly telling companies what they expect when a 483 observation is left at the end of the investigation. You just have to know where to look. This workshop will focus on the issues related to properly framing a response to the FDA and the processes that should be used to create the corrective actions required to meet the overall requirements clearly established in the new risk management era. Using Senior management roles as just one example, we will explore how the role of Senior Management is being defined. Regardless of whether or not the company is a "Mom and Pop" or a top 10 multinational company, FDA is clearly sending the message that Senior Management needs to pay more attention to key issues in Quality as much they do to the bottom line. We will evaluate the re-emphasized directions and provide best practices for your next 483 response.

## Workshop 3: Quality Oversight and Enforcement

Cristina De Simoni Klitgaard  
Stig Stovgaard

This workshop will introduce you to a real case on how a multinational pharmaceutical company introduced a sustainable Quality Oversight process after experiencing concerns raised by Health Authorities. You will benefit from the company's knowledge and learnings acquired during and after the quality oversight implementation process. There will be an interactive session with your peers where you will have the chance to discuss and share best practice, to inspire and to get inspired, and to learn about new tools and improvement opportunities.

## Workshop 4: Quality Risk as an Enabler for the Quality Management System

Sandy Ahern  
Lisa Robertson  
Milind Ganjawala, CDER FDA

This workshop is designed to discuss and explore how organizations define and ensure effective communication of risks within their governance structure and how they demonstrate risk maturity.

The workshop objectives are for attendees to:

1. share output around various methodologies used to describe and measure proactive risk as it relates to making quality decisions
2. share perspectives that demonstrate effectiveness of risk communication processes and escalation systems
3. understand the application and limitations of risk tools to determine quality decisions
4. share how risk maturity is or can be measured

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 29, 2018

### Morning Session: Moderator – Diane Alexander, CBER

8:30 – 9:00 **Behind the Numbers: Interpreting FDA Enforcement Statistics**

David Chesney

9:00 – 9:45 **Quality Metrics: The FDA & Industry Journey to Value**

Steve Greer

9:45 – 10:15 **CBER Compliance Update**

Melissa Mendoza, CBER

10:15 – 10:45 **CDER Compliance Update**

Donald Ashley, CDER

10:45 – 11:05 Break\*

11:05 – 11:35 **Office of Enforcement Update**

Scott MacIntire, OEIO, ORA

11:35 – 12:05 **Things I Really Wish Companies Would Do**

Alonza Cruse, ORA

12:05 – 12:45 **Ask FDA Q&A Session**

FDA Speakers

12:45 **Closing**

Mark Elengold

\*Denotes non-educational activity



## Continuing Education

This conference qualifies for 16.0 hours of continuing education credit.





# Registration

## 23rd Annual GMP By The Sea



### Fees

	<u>Industry</u>	<u>U.S. Gov't &amp; Press</u>
<b>EARLY DISCOUNT:</b> Payment Received By May 4, 2018	<input type="checkbox"/> \$2295	<input type="checkbox"/> \$1395
<b>NO DISCOUNT:</b> Payment Received After May 4, 2018	<input type="checkbox"/> \$2495	<input type="checkbox"/> \$1395

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](mailto: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  
**\$229 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. **Hotel reservations must be made on or before August 10, 2018, 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://aws.passkey.com/go/GMPByTheSea2018>

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:  
(830) 315-0055 • e-mail: [contactus@pharmaconference.com](mailto:contactus@pharmaconference.com)

**CLICK HERE TO REGISTER ON OUR SECURE SERVER**