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22nd Annual
GMP BY THE SEA

AUGUST 28 – 30, 2017 | CAMBRIDGE, MARYLAND

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The pharmaceutical and biologics industries are facing many changes with new technologies and challenges, FDA reorganizations, realignments and personnel changes.

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. For the last 21 years, it has been a meeting where senior FDA and industry speakers provide attendees the information they need to be successful.

Plenary sessions include keynotes by the new Director of the CDER Office of Compliance, the Director of CBER, and the Assistant Commissioner for Operations. The Office of Regulatory Affairs Program Directors will provide an update on the reorganization of the field from a geographic to product structure.

While the unique workshop format at GMP By The Sea is always a highlight, this year the plenary sessions will include summaries of the workshops so everyone can hear outcomes from ALL the workshops. Eight breakout 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. With topics such as quality metrics and culture, supply chain security, training and combination products, this opportunity will meet your most critical needs. Attendance by your whole organization will assure coverage of the many important subjects.

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

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.

### 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
About the Speakers

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

**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.

**Sarah Barkow, PhD** – Dr. Barkow is a Team Lead for Manufacturing Quality Guidance and Policy in CDER’s Office of Manufacturing Quality at the FDA, whose focus includes data integrity and medical gas. Dr. Barkow holds her Ph.D. in Physical Chemistry from MIT, where she worked on molecular motors in the laboratory of Robert Sauer. Prior to joining the FDA, she worked as a project lead for immunoassay development at Beckman Coulter.

**Ron Branning, BBA** – Mr. Branning has almost 50 years experience in the Bio/Pharmaceutical Industry and is currently SVP Quality, Dermira. His other recent industry positions have been Chief Quality Officer for Genzyme, VP Corporate Quality and Compliance Officer for Gilead and Global SVP Quality for Genentech. Mr. Branning brings a wealth of worldwide Quality experience in devices, drugs, biologics, and biotechnology and combination products in virtually all dosage forms. His career has been focused on resolution of significant quality issues and implementing Quality Systems that are designed to ensure compliance and rapid new product approval. Mr. Branning began his career in 1968 with J&J and began consulting as Ron Branning Consulting LLC, Quality Systems Compliance in 2007. He has served as Head of Corporate Quality for Genzyme, Gilead, Genentech, Aventis Behring, Somatogen and Serono. His other Quality management positions have been with Genetics Institute, Boehringer Ingelheim, GD Searle and Johnson and Johnson.

**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 worldwide.

**Chrissy Cochran, PhD** – Dr. Cochran is director of the Bioresearch Monitoring Program at the FDA and is responsible for working with each of FDA’s product centers to establish and manage the 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.

**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.

**Will Donovan, BS, MBA** – Mr. Donovan is the Global Quality Leader for 3M Drug Delivery Division. 3M has been innovating in drug delivery technology more than 50 years and has partnered with major pharmaceutical companies in both contract development and manufacturing of products. 3M’s main technologies focus on inhalation and transdermal delivered drug products. Mr. Donovan has been with 3M over 30 years with a majority of the time in quality leadership roles in 3M’s Health Care Businesses.

**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.

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Jennifer Finnegan McCafferty, PhD – Dr. McCafferty joined Merck & Co., Inc in May 2015 as VP of global External Quality Assurance. She started her career in 1995 as an analytical chemist with Merck and held site and central roles of increasing responsibility in Analytical Development, Quality, Stability, PAT and Regulatory CMC. In 2006, Dr. McCafferty moved to GlaxoSmithKline where she spent nine years as Head of GMS Laboratories Centre of Excellence, Product Quality Centre of Excellence, VP External Quality for the GMS pharma and consumer Supply Chains, and VP Consumer Healthcare Supply Chain Improvement Programme (CiP) to drive a step change in safety, quality and service across the supply chain.

Teresa Gorecki, BS – Ms. Gorecki is a Practice Lead at Compliance Architects LLC, and a proven senior-level leader with over 25 years of experience in Quality, Compliance, and Supply Chain. She excels at integrating quality strategy into business strategy to enable robust supply chain operations, successful commercialization of new products, and favorable regulatory compliance profiles. Prior to joining Compliance Architects, Ms. Gorecki was the Global Vice President for Business (Market) Quality at Janssen Pharmaceuticals, a position which capped a 27-year career in Quality Assurance with Johnson & Johnson.

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

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

Paula R. Katz, JD – Ms. Katz is Director of Manufacturing Quality Guidance and Policy in CDER’s Office of Compliance. She leads an interdisciplinary staff of senior compliance officers and technical experts who focus on cGMP enforcement and drug quality policy issues. Ms. Katz frequently advises Center and Agency leadership regarding manufacturing supply chain controls, contract manufacturing, data and application integrity, administrative law and procedure, and regulatory policy development and enforcement strategy. Ms. Katz has chaired Agency working groups and directed the development of guidance for industry, regulations, and legislation; managed responses to Congressional oversight and other stakeholder inquiries; and conducted domestic and international inspections, case evaluations, and enforcement actions. She is a frequent presenter at industry and agency meetings, conferences, and training events. Prior to joining FDA in 2009, Ms. Katz was a litigation associate at a large law firm in Washington, D.C., where her practice included regulatory compliance, white-collar crime, and general commercial litigation.

Mark D. Kramer, MS, RAC – Mr. Kramer leads Regulatory Strategies, Inc., a regulatory consultancy specializing in medical devices and combination products. He has more than 25 years experience in regulatory affairs, primarily at FDA, culminating in his position as Director of the Office of Combination Products from 2002 to 2007. From 2007-2010, Mr. Kramer was VP and Chief Regulatory Strategist at GE Healthcare. He was on the RAPS Board of Directors from 2009-2014 and is an adjunct faculty member for St. Cloud State University’s Master’s program in regulatory affairs.

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.

Mary Malarkey, BS – Ms. Malarkey is the Director of the Office of Compliance and Biologics Quality (OCBQ) in the Center for Biologics Evaluation and Research at the US Food and Drug Administration. OCBQ is responsible for ensuring the quality of products regulated by CBER over their entire lifecycle through pre-market review and inspection, and post-market review, surveillance, inspection, outreach and compliance. Her previous positions at CBER were Director, Division of Case Management from 2000-2005 and Branch Chief in the Division of Manufacturing and Product Quality (DMPQ) from 1996-2000. She worked in Research and Development in industry prior to joining FDA, and has been with CBER since 1989. She did laboratory work in both the Office of Therapeutics Research and Review and Office of Blood Research and Review prior to becoming a full time reviewer in 1993.

Register online at www.pharmaconference.com
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.

Ginette Y. Michaud, MD – Dr. Ginette Michaud is a hematologist with 20 years of regulatory experience in biological products and medical devices. Since March of 2016, she has served as the Director of the Biologics Program in the FDA’s Office of Regulatory Affairs. Prior to joining ORA, Dr. Michaud was the Deputy Director, Office of Blood Research and Review in the Center for Biologics Evaluation and Research.

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

Marci B. Norton, JD – Ms. Norton is a Senior Counsel in FDA’s Office of the Chief Counsel. Since 1995, she has provided legal counsel and advice to FDA personnel on matters concerning interpretation, application, and enforcement of the laws, rules, and regulations administered by the agency, including the Federal Food, Drug, and Cosmetic Act (FDCA) and the Public Health Service Act. Ms. Norton has handled civil enforcement actions, including injunctions, in rem forfeitures, and civil money penalty cases, and defended the agency in suits brought under the Administrative Procedure Act, the Freedom of Information Act, and the Federal Tort Claims Act. Ms. Norton has also worked with FDA’s Office of Criminal Investigations (OCI) and the Department of Justice in developing and prosecuting criminal violations of the FDCA and other related health care fraud statutes, and has worked as a counselor representing FDA’s Center for Devices and Radiological Health on legal matters involving medical and radiation emitting devices. Before joining FDA, Ms. Norton clerked for the Honorable Paul E. Alpert (retired) on the Maryland Court of Special Appeals.

Matthew Peplowski, BA, MS – Mr. Peplowski is a Director of Learning & Development at Sanofi Genzyme where he is working to establish effective learning and performance improvement programs. He has 24 years of experience, including Manufacturing, QA, and Training. Mr. Peplowski is an ATD certified instructional designer, PDA certified GMP training manager, former consultant, and Massachusetts Biotech Council instructor. He has taught extensively on Human Error Prevention, SOP Writing, GDP, cGMP, Investigations & CAPA, and other topics.

David G. Perkins, JD – Mr. Perkins joined AbbVie in 2009 as a Counsel, Corporate Legal Regulatory & Compliance. He has held several positions at AbbVie, including Director, Quality Management; Director, Quality Management Services; and Director Quality & Compliance. He assumed his current role as Director CMC Quality, in 2015. Prior to joining AbbVie, Mr. Perkins worked for the FDA for 10 years as a Chemist in the Chicago and Philadelphia Districts and then as a Drug Specialist Investigator in the Chicago District. Upon leaving FDA, he served as Legal Counsel at American Pharmaceutical Partners, Director of Regulatory Affairs/Regulatory Counsel at Cardinal Health, and Vice President of Quality and Facility Compliance at Sagent Pharmaceuticals.

Claudio Pincus, BS, MS – Mr. Pincus is the Founder and President of The Quantic Group, Ltd., a consulting firm recognized for providing strategies and implementing technical, compliance and quality programs for the pharmaceutical and medical device industries. His focus is on organizational and operational excellence, and he is a frequent lecturer on Quality Systems and Compliance Improvement programs. Mr. Pincus is a Fulbright Scholar, earning his Masters’ in Civil Engineering from Georgia Tech.

Brid Rooney, BSc, MPhil – Ms. Rooney is Head of External Manufacturing Quality Assurance for Biologics at Sanofi. She has 23 years of experience in biopharmaceutical operations, including roles in manufacturing, technical support, and quality assurance. In her current position she leads a team responsible for compliance oversight of Sanofi products manufactured, tested, and/or distributed by CMOs and business partners located in USA and Europe. She has experience in establishing effective Quality Agreements and maintaining successful partnerships throughout the product lifecycle from technology transfer and process validation into routine commercial production.

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About the Speakers

Cynthia Schnedar, JD – Ms. Schnedar, Executive Vice President of Regulatory Compliance at Greenleaf Health, provides strategic advice to clients in the life sciences industry. She was formerly Director of the Office of Compliance for FDA’s Center for Drug Evaluation and Research, where she spearheaded FDA’s efforts to protect the public health by ensuring companies comply with federal standards for quality and safety. Ms. Schnedar previously served at the Department of Justice in leadership positions on compliance and enforcement issues.

Gregg R. Sherman, BS, MSA, PMP – Mr. Sherman is a Senior Consultant at PAREXEL International who develops and implements strategic solutions to achieve compliance and quality goals for US and international clients. His skill and experience is defined by over 19 years of planning, managing, and executing global Quality Systems audits, systems integration, and GMP improvement initiatives and providing process and performance solutions to reduce compliance exposure and close systemic deficiencies. Mr. Sherman has given several presentations at pharmaceutical association meetings held by RAPs and PDA.

John Taylor, JD – Mr. Taylor is the President and a Principal at Greenleaf Health. He has over 25 years working on Food and Drug and health related issues at the FDA and in private industry. Prior to joining Greenleaf in 2014, Mr. Taylor served in three positions at FDA: Counselor to the Commissioner; Acting Deputy Principal Commissioner; and Acting Deputy Commissioner for Global Regulatory Operations and Policy. In 1991, he began his career at FDA. In 2005, Mr. Taylor left the Agency and spent four years working in the private sector, first as DVP for Federal Government Affairs at Abbott, then in 2007, as EVP for Health at BIO. He returned to FDA in the fall of 2009.

Brandon Varnau, BS – Mr. Varnau is Vice President and Head of Biologics Quality for Sanofi. He utilizes 25 years of experience in Biologics to lead all aspects of Quality Assurance, Quality Control and Compliance for nine Biologics sites in the US and EU. Prior to his current position, Mr. Varnau was Vice President and Head of Operations Quality, and prior to this he was Vice President of Quality at Genzyme’s Allston plant. He joined Genzyme in 2011 just after this site received a FDA consent decree. Prior to Genzyme, Mr. Varnau was Vice President of Quality for Bayer Health Care.

David H. Willis, PhD – Dr. Willis is a Senior Manager with Regulatory Affairs for Emergent BioDefense. The primary focus of this company is BioThrax® (Anthrax Vaccine Adsorbed), the only licensed anthrax vaccine in the United States. He has over 30 years of experience in the biologics, pharmaceutical and device industries, including Regulatory, R&D, pre-clinical, clinical and manufacturing.

Jennifer Zachary, JD – Ms. Zachary is a partner in Covington & Burling’s Washington, DC office, where she advises on compliance with FDA requirements for the development, manufacture, and sale of drugs and biologics, and assists clients with issues relating to GMP and GCP requirements, inspections, warning letters, recalls, import detentions, and compliance with the DSCSA. Before joining Covington, she served for six years as an Associate Chief Counsel for Enforcement in FDA’s Office of Chief Counsel.

Anthony Zook, PhD – Dr. Zook serves as Merck’s Executive Director Product Integrity, with responsibility for the development and execution of the Company’s Product Integrity strategy that protects the Merck products from external illicit actions. His work focuses the prevention, investigation, and forensic detection of pharmaceutical counterfeiting, diversion, theft, and tampering.

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.

Register online at www.pharmaconference.com
Monday, August 28, 2017
Morning Session: Moderator – Mark Elengold, Program Chairman

8:00 – 9:00 Registration
9:00 – 9:10 Welcome
9:10 – 9:40 CDER Update, Including Inspection Elements
   Donald Ashley, CDER
9:40 – 10:20 CBER Update
   Peter Marks, MD, PhD, CBER
10:20 – 10:40 Break*
10:40 – 11:10 ORA Update
   Ellen Morrison, ORA
11:10 – 11:45 FDA Program Realignment: Changes That Will Affect Industry
   Ellen Morrison, ORA and ORA Program Directors:
   • Pharmaceutical Quality Program Director: Alonza Cruse
   • Biologics Program Director: Ginette Y. Michaud, MD
   • Bioresearch Monitoring Program Director: Chrissy Cochran, PhD
11:45 – 12:15 Question and Answer Session
12:15 – 1:30 Lunch*

Afternoon Workshops

1:30 – 3:00 Workshop 1: Building a Quality Culture: Key Elements in Identifying Gaps and Building a Platform for Continuous Improvement
   Cynthia Schnedar
   Ron Branning
   The workshop will review universal key elements to ensure a quality culture and then move to more specific factors found in the ICH Q10 Pharmaceutical Quality System (QS) Elements Chart and FDAs current Metrics outline. The workshop will help you identify gaps and implement a platform for continuous improvement.

   Workshop 2: Adapting to the FDA's "Live Inspection" Approach
   Teresa Gorecki
   Brandon Varnau
   The FDA is adding a new, modern, significant approach to its arsenal of approaches for conducting site inspections. Forget about traditional front room-back room operations; the dynamics of supporting a “Live Review” are completely different. Teresa Gorecki and Brandon Varnau will step you through their first-hand experience and case examples for navigating the challenges presented by this new inspection approach.

   Workshop 3: Supply Chain Security
   John Taylor
   Anthony Zook, PhD
   This workshop will focus on processes, procedures, and tools directed to enhance global supply chain security. It will provide information to:
   • Create awareness to threats targeting the global pharmaceutical supply chain
   • Provide insight into world-wide regulatory trends related to securing the supply chain
   • Provide information to help companies update their quality management systems
   • Implement good import and export practices
   • Enhance product authentication and traceability

   Workshop 4: Combination Products
   Mark D. Kramer
   This session will explore the CGMP requirements for combination products that became effective in July 2013 and the recently issued final rule on postmarketing safety reporting for combination products. After an introductory presentation reviewing the requirements, participants will be encouraged to share their experiences implementing key provisions of these requirements (such as design controls), how to prepare for FDA inspections, and other combination product issues of interest.

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### Agenda

3:00 – 3:20 Break*
3:20 – 4:50 Workshops Repeated - the above workshops will be repeated
5:30 – 7:30 Networking Reception*

**Tuesday, August 29, 2017**

**Morning Session: Moderator – David Willis, PhD**

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<tr>
<th>Time</th>
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<tr>
<td>8:30 – 8:50</td>
<td>Workshop Reports</td>
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<td>8:50 – 9:25</td>
<td>Industry Perspective on the Changes in Regulatory and Enforcement Activities</td>
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<td>9:25 – 10:00</td>
<td>Data Integrity (Fixing)</td>
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<td>10:00 – 10:30</td>
<td>Quality Metrics</td>
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<tr>
<td>10:30 – 10:50</td>
<td>Break*</td>
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<tr>
<td>10:50 – 11:20</td>
<td>GMPs and Post-Market Safety Reporting for Combination Products: Guidance, Regulations, and Real World Activities</td>
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<td>11:20 – 11:50</td>
<td>Effective CMO/Sponsor Relationships</td>
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<tr>
<td>11:50 – 12:30</td>
<td>Question and Answer Session</td>
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<td>12:30 – 1:45</td>
<td>Lunch*</td>
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**Afternoon Workshops**

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<tr>
<th>Time</th>
<th>Workshop 1: Data Integrity (Fixing)</th>
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<tr>
<td>1:45 – 3:15</td>
<td>David Chesney, Sarah Barkow, CDER</td>
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Data integrity lapses are among the most serious concerns that pharmaceutical regulatory authorities have. Enforcement penalties can be severe from a business standpoint, and in extreme cases can even impact individuals who are held responsible for the occurrence of data integrity problems. In recent months the topic of data integrity has been in the forefront of concern among worldwide pharmaceutical regulatory agencies. This workshop will cover recent examples of data integrity issues and FDA actions resulting from them. The workshop will be co-led by a current international FDA expert and a former FDA enforcement official with over 20 years worldwide consulting experience.

**Workshop 2: Quality Metrics**

John Hyde and Claudio Pincus

Beyond time and numbers: Practical metrics for different levels in the organization. What are important Quality metrics by area or function? How does an organization aggregate and manage data for effective Quality System monitoring? How do you react to signals in Quality metrics? An interactive workshop, be prepared to discuss approaches at your company.


Agency Perspective: Paula Katz, CDER
CMO Perspective: Will Donovan
NDA Holder Perspective: Jennifer Finnegan McCafferty, PhD

This workshop will explore the rights and obligations associated with contract manufacturing from the perspective of a regulatory agency, the marketing authorization holder, and the contract manufacturer. Our discussion will focus on pragmatic strategies for contract manufacturing arrangements that can help ensure cGMP compliance and strong business relationships.

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Register online at [www.pharmaconference.com](http://www.pharmaconference.com)
Workshop 4: Implementing and Evaluating Effective Training Systems

This workshop is designed to discuss and explore how organizations define and ensure effective performance of GMP activities and how to demonstrate consistent training process and controls through documentation. The workshop objectives are for attendees to: 1) develop a philosophy around training methodologies to establish and measure performance; 2) provide evidence for compliance to demonstrate effectiveness of training processes, training systems and training controls; and 3) understand the application and limitations of training and human performance to resolve Quality issues.

3:15 – 3:35       Break*
3:35 – 5:05       Workshops Repeated - the above workshops will be repeated
6:00 – 8:00       Evening Social*

An informal gathering for drinks and dinner. Included in the price of your registration fee. Dress Casual.

Wednesday, August 30, 2017
Morning Session: Moderator – Diane Alexander, CBER

8:30 – 8:50       Workshop Reports
8:50 – 9:20       CDER Compliance Update
9:20 – 9:50       CBER Compliance Update
9:50 – 10:20      Office of Enforcement Update
10:20 – 10:40     Break*
10:40 – 11:20     Office of Chief Counsel Update
11:20 – 11:50     Regulatory/Legal Issues in the GMP Domain
11:50 – 12:30     Ask FDA Q&A Session
12:30            Closing

Donald Ashley, CDER
Mary Malarkey, CBER
Scott MacIntire, ORA
Marci Norton, OCC
Jennifer Zachary
Lori Hirsch
FDA Speakers
Mark Elengold

*Denotes non-educational activity

Continuing Education

This conference qualifies for 16.0 hours of continuing education credit.
22nd Annual GMP By The Sea

Fees

Early discount extended to May 31, 2017!

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<th>Industry</th>
<th>U.S. Gov't &amp; Press</th>
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<tr>
<td>EARLY DISCOUNT: Payment Received By May 1, 2017</td>
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<tr>
<td>NO DISCOUNT: Payment Received After May 31, 2017</td>
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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
$227 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 conferences dates. Hotel reservations must be made on or before August 11, 2017, 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/GMPByTheSea2017
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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