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Chesapeake Bay Hyatt
Cambridge, Maryland
August 10 – 12, 2015

20th Annual GMP By The Sea

Featuring our popular Maryland Eastern Shore Dinner evening!

Conference produced by

PHARMA CONFERENCE INC

Conference sponsored by

NIPTE The National Institute for Pharmaceutical Technology and Education

Improving quality and lowering costs of pharmaceuticals

ABOUT THE CONFERENCE

For 20 years, **GMP By The Sea** has provided a unique venue for the latest information about FDA's initiatives to improve the quality of pharmaceuticals and biologics. It hosted the first FDA presentation on the GMP's for the 21st Century program and many other important topics.

This year is no exception. Opening with keynote addresses from Associate Commissioner for Regulatory Affairs Melinda Plaisier, CBER Director Karen Midthun and CDER Office of Office of Pharmaceutical Quality Acting Deputy Director Lawrence Yu, to a concluding session of updates from the Office of Chief Counsel and senior compliance managers, the conference will offer unequaled opportunities to learn the current thinking of knowledgeable industry and FDA experts.

Plenary sessions will explain the goals and vision of CDER's new Office of Product Quality and how this reorganization will impact your firm's inspections and submissions. Other topics, fully described in the agenda, include data management and security, track and trace requirements, and an interactive discussion forum with the Office of Regulatory Affairs.

The unique workshop format at GMP by the Sea is always a highlight. Ten breakout sessions provide an opportunity to learn from FDA experts and industry colleagues informally. These are repeated, so you can attend two of the five offered each afternoon. Topics such as *CDER's New Inspection Protocol Project*, *Contract Manufacturing Organization and Management*, *GMP issues with Combination Products*, *Good Document Practices*, and *The Drug Quality and Security Act* 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 been considered the premier event of its kind, with unmatched opportunities to learn from and meet senior government and industry experts. Attend this year and you will understand why this is a conference has been a MUST attend event for 20 years.

WHO SHOULD ATTEND?

- Regulatory Affairs Professionals
- Quality Assurance Professionals
- Production Managers and Personnel
- Corporate Officers of Pharmaceutical and Biopharmaceutical Companies
- Financial Analysts Covering Pharmaceuticals

…basically, anyone involved with GMP matters related to pharmaceuticals or biopharmaceuticals

WHY ATTEND?

- To discuss "hot" topics with FDA officials
- To get FDA's latest thoughts on GMP matters
- To ask your questions and receive specific answers
- To interact with your peers on GMP matters
- To take valuable knowledge learned at the conference back to your company
- To network and interact with all regulatory officials present

Register online at www.pharmaconference.com

THE SPEAKERS

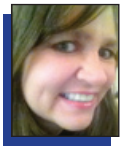
Diane Alexander, BS, MT(ASCP)SBB – Ms. Alexander serves as the Associate Director for Regulatory Policy with the Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research where she is responsible for policy development and review. She began her service with FDA in 1995 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.

John Avellanet, MS – Mr. Avellanet is an award-winning FDA compliance expert known for his business-savvy, pragmatic advice. Mr. Avellanet was the lead author of several certification courses on GMPs and Quality System Regulation (QSR) supplier management for the US Regulatory Affairs Professional Society (RAPS). Today, he serves as a lead expert in the ISPE's Data Integrity special interest group and was the industry expert reviewer for the 2014 updated international standard, *Evidential Weight and Legal Admissibility of Information Stored Electronically – Code of Practice for the Implementation of BS 10008*. He also recently co-authored the book, *Pharmaceutical Regulatory Inspections* (2014) along with several current and former regulatory agency officers, and his industry classic book, *Get to Market Now! Turn FDA Compliance into a Competitive Edge in the Era of Personalized Medicine*, was originally featured at BIO 2011.

Jeffrey Beck, BS – Mr. Beck began his career with the Genzyme Corporation in 2002 and transitioned to Sanofi Global Quality Supply Chain during the companies' merger in 2011. As the North American Head of Global Quality Supply Chain, he coordinates the quality, security and traceability of Sanofi products throughout the supply chain. Mr. Beck manages the compliance of Good Distribution Practices of both internal distribution centers and through auditing of external distribution partners. He develops Risk Management processes with tools and monitors compliance of packaging validation and transport qualification in his role at Sanofi. Mr. Beck's prior roles include Product & Supply Chain Risk Manager, where he managed the US Custom's C-TPAT program. He developed a mature Supply Chain Security program to include ISO 28000 standards on a global platform. Mr. Beck has experience with the TSA's CCSP program as well as consulting for Sanofi's European sites on the Authorized Economic Operators (AEO) Program. He also has experience managing a market monitoring program which included online pharmacies, high-risk and grey market regions for potentially diverted, re-imported and counterfeit drugs.

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

Ashley Boam, BS, MS – Ms. Boam currently serves as acting Director of the Office of Policy for Pharmaceutical Quality in the Office of Pharmaceutical Quality (OPQ) in the Center for Drug Evaluation and Research (CDER). The newly established Office of Policy 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. Before the formation of OPQ, Ms. Boam served as acting Deputy Director of the Office of Pharmaceutical Science for just over a year, focusing on regulatory and policy issues related to pharmaceutical quality assessment. Prior to joining CDER, 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.



Marlene Bobka, BS, MLS – Ms. Bobka is Senior Vice-President and member of the Board of Directors at FOI Services, Inc., a privately-held firm she joined in 1985. She is responsible for functions facilitating access to FDA records acquired using the Freedom of Information Act as well as producing teleconferences which interpret FDA regulations, actions, and expectations. She is a frequent author and speaker on topics offering insight into finding and using fugitive drug, device and biologic regulatory information and has addressed audiences worldwide for organizations including the Drug Information Association, AdvaMed, the Regulatory Affairs Professional Society, the Special Libraries Association, the American Chemical Society, the Association of Food and Drug Officials and many others. Before joining FOI, Ms. Bobka taught online searching strategy, conducted extensive medical, chemical, and government literature research and designed and documented databases at Bibliographic Retrieval Services and the National Cancer Institute.

Panos Boudouvas, BS, MBA – Mr. Boudouvas started ZenQMS to provide quality professionals better electronic Quality Management System (eQMS) tools for enhanced compliance at an affordable price. Prior to the QAB, Mr. Boudouvas served in multiple executive roles at Aptuit, a leading Pharma CRO/CMO, where he was a member of the Executive Committee and Vice President of Operational Excellence responsible for the worldwide launch and management of Aptuit's LeanSixSigma program as a certified LeanSixSigma Black Belt. Mr. Boudouvas was one of the first employees at Aptuit, leading the corporate development effort through a broad acquisition program. He also served as Director of Facilities & Capital Development, which included global responsibility for 16 facilities, more than 100 full-time staff members, a ~$50 million annual operating budget and several multi-million dollar facility expansion and maintenance projects. Prior to Aptuit, he served multiple roles in Private Equity and Investment Banking firms, with a focus on the pharmaceutical, healthcare services and technology industries.

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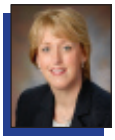
THE SPEAKERS

David L. Chesney, BS – Mr. Chesney is 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. Since joining PAREXEL, Mr. Chesney has provided compliance consulting and training services to clients worldwide. He presently heads PAREXEL's Strategic Compliance Consulting group, providing services to the pharmaceutical, medical device and biotechnology industries, and the Food and Drug legal community.

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

David Doleski, BS – Mr. Doleski, Acting Deputy Director, OPF, OPQ, has been with FDA for 24 years. He most recently served as director of the Division of Good Manufacturing Practice Assessment, which is responsible for overseeing the pre-approval inspection program for new and generic drugs, and reviews and inspections for biologic products. He was an acting branch chief and team leader in CBER's Division of Manufacturing and Product Quality. As a reviewer and inspector, he performed numerous CMC reviews and pre-approval inspections for biologic drug substances and drug products. He also served as an acting team leader in the Office of Legislation in the Office of the Commissioner.



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

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

PHOTO NOT AVAILABLE

Kerry Hawitt, PhD – Dr. Hawitt is the Head of Product Quality Management providing strategic direction and tactical support for Product Quality Management at Shire. She joined Shire in 2006 as Manager for International QA based in the UK and through her time at Shire, Dr. Hawitt has served various roles in the International QA team and then Head of Global Quality Compliance. She brings to Shire 20 years of relevant experience including several roles at Eli Lilly and Mallinckrodt Veterinary. Over the years, Dr. Hawitt has covered a wide range of formulations from solid oral dosage forms, parenterals, biotech and combination products, travelling extensively throughout the United States and the EMEA region.

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.

THE SPEAKERS

PHOTO NOT AVAILABLE

Teddi E. Lopez, BS, MA – Ms. Lopez has been with the FDA for 19 years and is the Director of the Division of Quality Surveillance Assessment in the Office of Surveillance within CDER's Office of Pharmaceutical Quality. She manages a group that is responsible for compliance strategy. Previously, Ms. Lopez was the Director of the Division of Domestic Drug Quality in Office of Manufacturing and Product Quality within CDER's Office of Compliance.

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

Grace McNally, BS – Ms. McNally is a Branch Chief (acting) in CDER's Office of Pharmaceutical Quality, Office of Process and Facilities (OPF), and oversees facility and process sections of integrated reviews and inspection activities associated with pending NDA, ANDA and BLAs. Ms. McNally served previously as Branch Chief, Regulatory Policy and Collaboration Branch, in CDER's Office of Compliance, and as a Senior Policy Advisor and Compliance Officer. In these roles, she prepared CGMP cases, participated in revising CGMP regulation, developed policy and guidance in the areas of process validation, combination products, quality systems, and manufacturing science. Prior to coming to CDER, she was a field investigator in Philadelphia District and later the Denver District, specializing in pharmaceutical and medical device inspections.

Karen Midthun, MD – Dr. Midthun is the Director of the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration. Dr. Midthun previously served as the Deputy Director of CBER and the Director of the Office of Vaccines Research and Review within CBER. Before joining the FDA in 1993, Dr. Midthun was on the faculty of the Department of International Health at the Johns Hopkins Bloomberg School of Public Health, where she was involved in the clinical development of investigational vaccines and was an attending physician at the Johns Hopkins Hospital.

Christine Moore, PhD – Dr. Moore is currently the Acting Office Director of the Office of Process and Facilities (OPF), within the Office of Pharmaceutical Quality, in CDER. OPF ensures quality is built into the manufacturing processes for new drugs, generic drugs and biotech products by providing oversight of process review, microbiologic review and pre approval inspections. In her 10 years at FDA, She has served as branch chief, deputy office director and office director in CDER's Office of New Drug Quality Assessment. Within FDA, she has been at the forefront of advancing regulatory and scientific approaches for Quality by Design, Process Analytical Technologies (PAT) and innovative manufacturing technologies, with substantial contributions to international harmonization efforts. Prior to FDA she worked at Pfizer and Searle/Pharmacia in API process development, scale-up, PAT and tech transfer.

Alicia Mozzachio, PharmD – Dr. Mozzachio is currently the Acting Division Director in the Office of Policy for Pharmaceutical Quality (OPPQ) within the newly formed OPQ in CDER. The division will be working on guidance for industry, regulation changes and compendial/ standards organization collaboration. Dr. Mozzachio's prior experience includes serving as the Branch Chief for the International Compliance Branch 1 within the Division of International Drug Quality (DIDQ), Office of Manufacturing and Product Quality (OMPQ), Office of Compliance (OC). Her branch was responsible for evaluating FDA's international drug inspection reports and determining the actions to be taken against firms failing to comply with CGMP. She has been with the FDA for 20 years in various job roles and locations. She began her career as a junior level investigator with FDA and distinguished herself as a Drug Specialist within her organization before accepting a new position with CDER's then known Foreign Inspection Team. In addition to her FDA roles and responsibilities, Dr. Mozzachio has deployed with the Public Health Service (PHS) to provide aid to victims impacted by disasters.

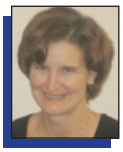
Sharon O'Callaghan, BS – Ms. O'Callaghan is a Consumer Safety Officer with the Division of Inspections and Surveillance, Office of Compliance, Center for Biologics Evaluation and Research (CBER). She joined FDA in 1988 as a medical technologist and has managed the Biological Product Deviation (formerly Error and Accident) Reporting System since 1990. Ms. O'Callaghan was instrumental in developing the final rule on reporting Biological Product Deviations, published November 7, 2000.

Edward Patten, MS – Mr. Patten is the Associate Director Manufacturing Science in the Office of Compliance and Biologics Quality, CBER, FDA. He has been with the CBER since July 2008. Mr. Patten regularly works with the Office of Combination Products, including the Part 4 regulation as well as the Guidance for CGMP for Combination Products. Prior to joining FDA, he spent over 25 years in Regulated Industry.

THE SPEAKERS

Melinda Plaisier – Mrs. Plaisier serves as the Associate Commissioner for Regulatory Affairs (ACRA). She has responsibility for more than 4,600 staff and for all operations conducted by the Office of Regulatory Affairs (ORA), Global Regulatory Operations and Policy. Mrs. Plaisier began her career in public policy, working in the U.S. Congress for more than a decade. She joined FDA in 1995, spending more than 13 years in the Office of the Commissioner. There she served as the Associate Commissioner for Legislation, providing executive leadership in directing and managing the agency's congressional relations and legislative activities. She also served as the Associate Commissioner for International Programs, where she focused on negotiating international agreements and working with developing nations. Prior to her appointment as ACRA, she served as the Regional Food and Drug Director (RFDD), Central Region.

Sarah Pope Miksinski, PhD – Dr. Pope Miksinski is the Acting Director of the FDA's Office of New Drug Products (ONDP), in the Office of Pharmaceutical Quality (OPQ). She joined FDA nearly 13 years ago, serving initially as a Chemistry Reviewer for reproductive/urologic drugs. Since that time, she has held additional positions within ONDQA including Chemistry, Manufacturing and Controls Lead as well as Branch Chief and Division Director. Dr. Miksinski's areas of technical expertise include the characterization of complex drug substances/products, manufacture of injectable dosage forms, and spectroscopic methodology. During her years at FDA, she has been active in numerous quality initiatives including the integration of review/inspection, the Pharmaceutical Inspectorate, and the development of enhanced collaborative approaches to facilitate the review of urgently needed drugs.



Anita Richardson, BS, MAS – Ms. Richardson serves as the Associate Director for Policy in CBER's Office of Compliance and Biologics Quality, where she leads a team that is responsible for policy development and review, CBER shortages, and import monitoring. She joined CBER's Office of Compliance, Division of Case Management, in 1990 after eight years of professional experience in the blood banking industry. Ms. Richardson worked as a compliance officer for 10 years and was responsible for the review, analysis and processing of administrative, civil and criminal enforcement actions. From 2000 to 2003, She served as Director of the Compliance Branch in the Baltimore District Office.

Susan Rosencrance, PhD – Dr. Rosencrance is the Acting Director for the Office of Lifecycle Drug Products in the newly formed Office of Pharmaceutical Quality. In this capacity she directs procedures for developing and implementing review policies to assure drug product quality during the lifecycle of both brand and generic drug products. Prior to joining the Agency, Dr. Rosencrance worked at Merck & Co.'s Research and Development Laboratories in Rahway, New Jersey. She joined the Office of Generic Drugs as a chemistry reviewer in 1991 and has held various roles within the Office of Generic Drugs including reviewer, senior reviewer, team leader, deputy division director, and deputy office director for chemistry.

Kelsey Schaefer, BA, JD – Ms. Schaefer is an Associate Chief Counsel for Enforcement at the Food and Drug Administration (FDA). She works 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. She has also served as lead agency counsel on civil enforcement matters and 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. Prior to joining FDA, Ms. Schaefer worked for 12 years at a top 100 law firm working on numerous cases involving FDCA issues. She also worked with the Manatee County Public Defender's Office handling numerous felony cases pro bono.

Nancy Singer, BS, JD, LL.M – Ms. Singer is president of Compliance-Alliance LLC. She teaches FDA officials how to improve their written and oral communications practices. She also teaches drug and device industry employees how to write their compliance story and avoid phrases that will embarrass the employee and reflect negatively on the company. Ms. Singer began her career as an attorney with the United States Department of Justice where she did litigation for the Food and Drug Administration. Subsequently she was a partner at the law firm of Kleinfeld, Kaplan and Becker.

Lawrence Yu, PhD – Dr. Yu is the Deputy Director, Office of Pharmaceutical Quality, Food and Drug Administration. He is also adjunct Professor of Pharmaceutical Engineering at the University of Michigan. Prior to joining the FDA, Dr. Yu worked at Pfizer (Upjohn) and GlaxoWellcome for 8 years. Dr. Yu joined the FDA in 1999 and has served as Team Leader, Deputy Division Director, Division Director, and Deputy Office Director. Dr. Yu's research interests have centered on the prediction of oral drug delivery and the development of pharmaceutical Quality by Design. His compartmental absorption and transit (CAT) model has laid the foundation for the commercial software, GastroPLUSTM and Simcyp®, which are being widely used in the pharmaceutical industry.

Sherry Zhang, MA, MBA – Ms. Zhang joined Shire Pharmaceuticals in 2012 responsible for External Inspections, Internal and Vendor Audits, Product Quality Review, Document Management and Training for the GMP/GDP operations. In 2013, she transitioned to the role of Head of Quality Systems responsible for Quality Manual, Global Quality Standards, Quality Risk Management, Document Management, Training, and CAPA/Deviation/Change Control systems. Prior to joining Shire Pharmaceuticals, Ms. Zhang worked in diverse areas of quality systems remediation, quality control, and product development for 17 years.

AGENDA

Monday, August 10, 2015

Morning Session: Moderator – Mark Elengold, Program Chairman

8:00 – 9:00	Registration	
9:00 – 9:10	Welcome	
9:10 – 9:40	**Keynote: CDER Sr. Management**	Lawrence Yu, PhD, CDER
9:40 – 10:10	**Keynote: ORA Sr. Management**	Melinda Plaisier, ORA
10:50 – 11:20	**Keynote: CBER Sr. Management**	Karen Midthun, MD, CDER
11:20 – 11:40	Break*	
11:40 – 12:10	**Industry Expectations**	Jacqueline Elbonne, PhD
12:10 – 12:30	**Question and Answer Session**	Morning Speakers
12:30 – 1:45	Lunch*	

Afternoon Session: Workshops

1:45 – 3:15	**Combination Products**	Kerry Hawitt Edward Patten, CBER
	Post-Market Surveillance Reporting	Sharon OCallaghan, CBER
	Design Considerations for Electronic Quality Management Systems (QMS)	Teddi Lopez, CDER Panos Boudovas ORA TBA
	Implementing a Corporate-Wide Quality Vision	Sherry Zhang
	Contract Manufacturing Organization Management	John Hyde Gary Bird, PhD
3:15 – 3:35	Break*	
3:35 – 5:05	**Workshops Repeated – the above workshops will be repeated**	
5:30 – 7:30	**Special 20th Anniversary Networking Reception***	
	Drinks and hors d'oeuvres for two hours. Will be a fun time outdoors, weather permitting.	

Tuesday, August 11, 2015

Morning Session: Moderator – David Chesney

9:00 – 9:45	**Office of Pharmaceutical Quality (OPQ) – Quality Pre-Market Review Process: Integrated Quality Assessment**	Sarah Pope-Miksinski, PhD, CDER and Susan Rosencrance, PhD, CDER
9:45 – 10:30	**OPQ's Office of Process and Facilities: Integration of Process Review and Pre-Approval Inspection**	Christine Moore, PhD, CDER
10:30 – 11:00	**OPQ – Questions and Answers**	Morning CDER speakers
11:00 – 11:20	Break*	
11:20 – 11:50	**Implementing an Effective Corporate Data Integrity Program**	John Avellanet
11:50 – 12:20	**Implementing Track and Trace (GDP)**	Jeffrey Beck
12:20 – 12:45	**Question and Answer Session**	Morning Speakers
12:45 – 2:00	Lunch*	

AGENDA

Afternoon Session: Workshops

2:00 – 3:30	**Inspections and Audits: Assessment and Scoring Methods from an Industry Perspective**	Dave Chesney David Doleski, CDER
	Ensuring an Effective Data Integrity Chain-of-Custody	John Avellanet
	Guidance Initiatives – CDER	Ashley Boam, CDER Alicia Mozzachio, CDER
	Drug Quality and Security Act (DQSA) – Track and Trace	Jeffrey Beck Anita Richardson, CBER
	Good Document Practices	Nancy Singer Marlene Bobka
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, dinner and a lot of good food including steamed crabs, barbecue chicken and steaks. Included in the price of your registration fee. Dress casual.

Wednesday, August 12, 2015

Morning Session: Moderator – Diane Alexander

8:30 – 9:00	**Office of the Chief Counsel Update**	Kelsey Schaefer, OCC
9:00 – 9:30	**Current CBER Compliance Initiatives**	Mary Malarkey, CBER
9:30 – 10:00	**CDER Office of Compliance Update**	Tom Cosgrove
10:00 – 10:20	Break*	
10:20 – 10:50	**OE Enforcement**	ORA TBA
10:50 – 11:50	**Ask the ORA Q&A Session**	ORA PANEL
11:50 – 12:15	**Question and Answer Session**	

*denotes non-educational activity

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The University of Maryland School of Pharmacy is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Statements of credit will be mailed within 60 days to those participants who successfully complete the activity. Successful completion requires participation at the entire activity and completion of an activity evaluation form. No partial credit will be awarded. This activity is cosponsored by NIPTE.

THE VENUE

Located on the scenic Eastern Shore of Maryland, the Hyatt Regency Chesapeake Bay Golf Resort, Spa and Marina is the area's finest full-service, year-round resort. Built in 2002 on over 342 acres, the 400 room resort features an 18-acre nature preserve with guided hikes and wildlife observation, an 18,000 square foot European Health Spa, a glass-enclosed pool and lounge area, an 18-hole Keith Foster designed championship golf course, and a 150-slip marina.

Cambridge, Maryland is 74 miles southeast of BWI Airport, 90 miles southeast of Ronald Reagan Washington National Airport, and 95 miles southeast of Dulles. For exact directions to the hotel, please log on to http://chesapeakebay.hyatt.com/hyatt/hotels/services/maps/index.jsp?icamp=propMapDirections

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ANNOUNCING

1st Annual

GMP By The Sea Europe

September 7 – 9, 2015

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The top pharmaceutical conference in the United States…now coming to Europe! The brightest regulatory authority and industry minds come together in September for Pharma Conference Inc's **1st Annual GMP By The Sea Europe**. Mark your calendars for this must-attend conference that will provide unmatched opportunities to learn from and meet an impressive slate of senior government and industry experts who will present the most current and critical information available anywhere.

The conference brochure will be available on PharmaConference.com in early April.

Please share this with your European counterparts!

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EARLY REGISTRATION FEE DISCOUNTS will be announced soon!

HOTEL EARLY BIRD SPECIAL EUR 125,00: Good through May 31, 2015. After this date rate changes to EUR 145,00 per room per night. Both rates are incl. breakfast and excl. city tax at EUR 4,60 per person per night.

REGISTRATION

20th Annual GMP By The Sea

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FEES

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	Industry	Gov't & Press
Payment Received By June 1, 2015	❑ $2095	❑ $1195
Payment Received After June 1, 2015	❑ $2295	❑ $1195

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

Cancellation Policy: 30 days or more for a full refund less $250 cancellation fee; under 30 days, no refund, but attendee substitutions may be made at any time. Cancellations and substitutions must be made in writing to Pharma Conference (email registration@pharmaconference.com). In the event of any civil disorder, extremely adverse weather conditions, or other Acts of God, Pharma Conference reserves the right to reschedule the meeting dates in the interest of attendee safety.

PAYMENT

Full payment may be made by credit card or company check

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

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

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

HOTEL

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Chesapeake Bay
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(410) 901-1234
Single/Double rate $219

A limited number of rooms have been blocked at the special rate below per night (single or double). Hotel reservations must be made **on or before July 24, 2015** in order to guarantee the special rate. Individuals are responsible for making their own hotel reservations. Be sure to mention the name of the conference and Pharma Conference Inc when making your reservation in order to be properly identified with the conference. **Please do not use travel agents for reservations.**

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