

The top GMP conference in the U.S.!

27<sup>TH</sup> ANNUAL  
GMP BY THE SEA

AUGUST 14 – 16, 2023 | CAMBRIDGE, MARYLAND  
Hyatt Regency Chesapeake Bay Hotel

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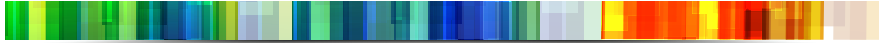
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# About the Conference



**GMP By The Sea** is known as the premier, must-attend conference for anyone in quality, regulatory affairs, manufacturing or related positions. This year will be no different as it continues to be a meeting where senior FDA and industry speakers provide attendees the information they need to be successful and the tools they need to navigate the changes and challenges in the pharmaceutical and biologics industries.

This year we open with a story about going from pharma executive to patient, a perspective not yet given at this conference. An excellent reminder of how important our work is. Then we have 14 FDA speakers (both invited and confirmed) representing CDER, CBER and ORA, as well as top industry experts who will focus on the issues in the changing world of GMP compliance which affect you and your company. This includes FDA Center Updates from CDER, CBER and ORA, plus CDER and CBER's Office of Compliance updates. Other topics covered in the plenary sessions include warning letters, a panel on communicating with FDA on GMP issues, the future of manufacturing and continuous manufacturing, quality management maturity, and several other important topics.

The unique workshop format at **GMP By The Sea** is always a highlight. Eight breakout sessions provide an opportunity to learn from FDA experts and industry colleagues informally. These are repeated, so you can attend two of the four offered each afternoon. Topics such as Oversight of Contract Manufacturers, Deviations – Turning Failures into Quality & Business Success, Implementing a Quality Management Maturity Program, and Phase Appropriate GMPs Considerations 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 (including 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 ONE conference many attend every year. Attend with your team to get the information needed to assure your firm is current!



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

# About the Conference

## Who Should Attend?

- Anyone involved in FDA inspection preparation, hosting, or responses including production, quality assurance, quality control, regulatory affairs, or auditing in the pharmaceutical and biopharmaceutical industry in Regulatory and GMP matters.
- Supervisory personnel and managers can enhance Regulatory and GMP performance by sending production, quality, and regulatory personnel to this learning experience. They will gain a significant appreciation of FDA's inspectional approach, and they will learn the critical skills needed to prepare for and properly host inspections.
- Anyone who wants an exceptional GMP learning experience and a fun time

## Why Attend?

- To gain a better understanding of how the Regulatory Authorities look at your operations and how to anticipate problem areas before they create problems for your company during the inspection
- To take advantage of the knowledge of seasoned FDA and industry experts who have "been there and done that"
- To obtain current information about FDA activities
- To get those cGMP questions that cause you sleepless nights answered by the experts

### ***Last year's attendees had high praise for the conference:***

*"This conference is the best. I really appreciate all the FDA talks. I've been to no other conference with such an ear to what FDA is thinking and from their mouth want!"*

*"Loved the repeated sessions. Loved the workshops."*

*"The relevance and information were invaluable. Especially love that each speaker always brought it back to dedication to patient safety."*

*"I loved the case scenarios and workshops."*

*"Excellent, informative, and useful content and presentations!"*

## About the Venue

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

Cambridge, Maryland is 79 miles southeast of BWI Airport, 90 miles southeast of Ronald Reagan Washington National Airport, and 117 miles southeast of Dulles. For exact directions to the hotel, please log on to <https://chesapeakebay.regency.hyatt.com/en/hotel/our-hotel/map-and-directions.html>



# About the Speakers



**Maria C.H. Anderson, BS, MS** – Ms. Anderson is Chief of the Biological Drug and Device Compliance Branch in the Division of Case Management, within the Office of Compliance and Biologics Quality, at the Food and Drug Administration's Center for Biologics Evaluation and Research (CBER). Her branch is responsible for the review and evaluation of compliance and enforcement actions for biological products, drugs, and devices regulated by CBER and for the coordination of CBER's import and export programs.



**Raymond A. Bonner, BA, JD** – Mr. Bonner is Partner at Sidley Austin LLP. He founded the firm's Food, Drug and Medical Device Compliance and Enforcement practice and is a member of the firm's Executive Committee. He concentrates his practice on representing life science companies in connection with government investigations, enforcement proceedings and litigation. These investigations and related enforcement matters involve a range of matters including clinical studies, marketing practices, pricing and reimbursement, product safety and reporting, good manufacturing practices (GMP), quality system regulation (QSR), and HACCP. Prior to joining Sidley, Mr. Bonner served as an Assistant United States Attorney in the District of Maryland for six years, where he prosecuted pharmaceutical application and GMP cases and litigated other FDA-related cases. Throughout his tenure as a prosecutor, he counseled FDA and its Special Prosecution Staff investigating the healthcare industry. Mr. Bonner is the recipient of the FDA's Harvey W. Wiley Medical and Commissioner's special citation.



**David L. Chesney, MSJ** – Mr. Chesney is the Principal and General Manager for DL Chesney Consulting, LLC, Cumberland Foreside, Maine. He is a worldwide expert in GMP/GCP compliance, investigations, and training, with 30+ years in Industry and 23 years in FDA. Previously, Mr. Chesney served for over 20 years as Vice President and Practice Lead, Strategic Compliance Services for Parexel Consulting. Prior to joining Parexel Consulting, he served 23 years with the FDA as an Investigator, Supervisory Investigator, Director of Investigations and ultimately as District Director in San Francisco, Mr. Chesney is a member of PDA, where he serves on the faculty of the PDA Training and Research Institute. He is a member of the Food and Drug Law Institute, where he serves as the faculty for FDLI's continuing education programs.



**Alexander Chung, PhD** – Dr. Chung currently holds the position of Head of Continuous Improvement within the Global Quality organization of GSK Vaccines, driving effective strategy deployment and engagement across all Global manufacturing sites, by implementing simple, efficient, practical, and sustainable solutions. In his previous roles, he was Program Lead for the Global Safety and Quality Culture Program at GSK Vaccines. It was here where he co-developed and initiated the Quality Culture Journey for GSK Vaccines. Dr. Chung holds a PhD in Molecular Biology and 11+ years of experience in the pharmaceutical industry in GMP, GCP, and non-regulated Preclinical environments.



**Robert Darius, BS** – Mr. Darius is the Head of Quality Rare Disease, Oncology & Immunology Cluster at Sanofi. Previously, he served as Senior Vice President of Quality at Novavax Vaccines. Prior to that, Mr. Darius was Vice President of the Global Quality Unit in GSK Vaccines for North America and Germany for 11 years. He served for 15 years in the US FDA Center for Biologics Evaluation and Research, Division of Manufacturing and Product Quality, as Lead Reviewer & Inspector. He also served as Special Assistant on Counter Bioterrorism issues, reporting to the CBER Director. Mr. Darius is a Microbiologist by training and graduated from George Mason and Johns Hopkins Universities.



**David Elder, BS, EE** – Mr. Elder, Principal at Greenleaf Health, Inc., has more than 34-years of extensive regulatory experience. At Greenleaf, he provides strategic guidance and support to pharmaceutical and medical technology companies. Mr. Elder is a 23-year veteran of the FDA, where he held the following positions: Investigator, Compliance Branch Director, Director of the FDA Office of Enforcement, and Director of the FDA Office of Regional Operations.



**Lynne Ensor, PhD** – Dr. Ensor is Senior Vice President, Head of Global Strategic Compliance Consulting for Parexel International. She has been a consultant to the biopharmaceutical industry since 2019, with expertise in sterile product manufacturing, regulatory strategy, and manufacturing facility remediation to ensure regulatory compliance. Dr. Ensor is currently a member of the U.S. Pharmacopeia Microbiology Expert Committee (USP 2020-2025 Council of Experts). She was previously employed by the FDA for 21 years, including having served as the Deputy Office Director in the Office of Process and Facilities/OPQ/CDER. Her prior experience includes Roche Biomedical Laboratories, the Discovery Channel, and the University of Maryland's School of Medicine.

# About the Speakers



**Amnon Eylath, BS, MS** – Mr. Eylath is a seasoned Quality Leader who is experienced in the complete life cycle of Small Molecule and Biological drug development: from discovery, through nonclinical and Tox studies, clinical trials, process and method development, GMP manufacturing, validation, regulatory submissions and US/EU/MHRA commercial product approvals. He has direct experience with process development, validation and QA/QC oversight for Cell Therapies and for therapeutic Monoclonal Antibodies and has led or supported cross-functional Continuous Improvement and Gap-Remediation initiatives and projects. Mr. Eylath is an international thought-leader on Phase-Appropriate application of GMP to drug development and manufacturing and has presented seminars and training at PDA and ISPE events, as well as presenting on sterilization technology to CBER/CDER. He holds a lean-Six Sigma Black Belt (Amgen) and is Past President of the New England PDA chapter.



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



**Steven A. Greer, BS** – Mr. Greer is a Senior GMP consultant and GMP Business Development Leader for ESI. He is also an engaging and inspiring keynote speaker, and executive coach working with Fortune 50 to small businesses. Mr. Greer speaks on leading change, improving performance, and increasing employee engagement. He “graduated” two years ago after more than 35 years at the Procter & Gamble Company where his last role was the External Engagement Leader in Corporate Quality Assurance. His career included leadership roles in manufacturing and quality spanning P&Gs pharmaceutical, health & beauty and home care businesses. In his last role he was responsible for building collaborative relationships with the FDA and industry as well as strengthening internal capability.



**Al Habib, BS** – Mr. Habib is the Head of Global Quality, GxP IT Quality Assurance at Bristol-Myers Squibb. He has over 24 years of pharmaceutical industry experience and 29 years of experience in Information Technology. Mr. Habib has extensive experience in IT computing controls, enterprise architecture, electronic records and signatures controls, and data integrity. Before BMS, he worked as an immunology scientist at Medarex before pivoting to IT to support laboratory and manufacturing technology implementations and validation.



**Kir Henrici, BS** – Ms. Henrici, CEO, The Henrici Group (HG), has been consulting domestically and internationally for 13 years in support of quality and compliance, with specialized focus and expertise in the area of Digital Transformation, Quality Culture and organizational change, Quality Management Systems (QMS), and Data Governance/Data Integrity Assurance. She has gained global and diverse perspective and working knowledge of quality, compliance and technical challenges and solutions impacting companies around the world, supporting a range of initiatives including tactical change in the area of Quality Culture, QMS design and remediation, and global/site data governance programs. Ms. Henrici is a member of PDA and ISPE, and currently serves as a member of the PDA Regulatory Affairs/Quality Advisory Board (RAQAB). She is also the co-lead for the PDA “Big Data” task force and PDA Data Integrity Interest group and is currently co-leading the PDA team submitting comments in response to the FDA Discussion Paper: Artificial Intelligence in Drug Manufacturing.



**John M. Hyde, BS, BBA, MS** – Mr. Hyde is a Senior Principal Engineer and Founder of Hyde Engineering + Consulting, Inc., a firm of over 250 engineers and scientists, founded in 1993 and specializing in process engineering, process and equipment validation, operational sustainability and regulatory compliance consulting for biopharmaceutical and pharmaceutical manufacturers. Hyde Engineering + Consulting, Inc. has operations in the United States, Europe, Canada, India, Malaysia and Singapore. Prior to the formation of Hyde Engineering + Consulting, Inc., Mr. Hyde was Senior Project Engineer with Synergen, a biopharmaceutical research and manufacturing company. His work at Synergen included design, start-up and validation of key process systems and the overall responsibility for the cleaning validation programs for the firm’s large scale and clinical manufacturing facilities. From 1982 to 1992, he 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. Mr. Hyde has presented papers at numerous engineering conferences and short courses on topics including biopharmaceutical process systems design, automatic cleaning system design and implementation, and control system design for pharmaceutical processes, and he has published numerous articles on these topics.



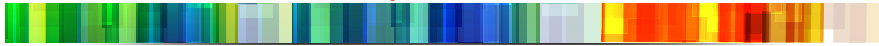
**Michael LaBruto, MS** – In his current role at the University of Pennsylvania Gene Therapy Program (GTP), Mr. LaBruto leads the Quality Assurance organization that supports the development and commercialization of novel genetic based therapeutics. He has over 25 years of experience in the development and implementation of cGMP Quality Systems, supporting both small molecule and biologic manufacturing/testing facilities. Prior to joining UPenn, Mr. LaBruto spent 15 years at GSK, where he held a variety of senior leadership roles within Quality Assurance, most recently, serving as the Executive Director of Quality for the One Pharma Supply Chain, including R&D Operations. He currently serves on the PDA/FDA planning committee supporting the annual joint regulatory conference.



**Jennifer A. Maguire, PhD** – Dr. Maguire is the Director of the Office of Quality Surveillance/OPQ/CDER/FDA which assesses intelligence throughout the product lifecycle to inform stakeholders about the state of pharmaceutical quality. During her tenure, Dr. Maguire has contributed to initiatives aimed at modernizing the regulation of pharmaceutical manufacturing and product quality including QbR, QbD, ICH Q12, Site Selection Model, Advanced Manufacturing, Quality Metrics and Quality Management Maturity. Dr. Maguire has a BS in Chemical Engineering from the University of Virginia and a PhD in Industrial and Physical Pharmacy from Purdue University.



# 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. Dr. Marks has worked in academic settings teaching and caring for patients and in industry on drug development and is an author or co-author of over 100 publications. He joined the FDA in 2012 as Deputy Center Director for CBER and became Center Director in 2016. Over the past several years Dr. Marks has been integrally involved in the response to various public health emergencies, and in 2022 he was elected a member of the National Academy of Medicine.



**Niraj Mehta, PhD** – Dr. Mehta is the Executive Director/Global Quality Lead for Strategic Programs and Regulatory Intelligence team within Merck's Manufacturing Division (MMD). He is responsible for the management of external policy, and execution of processes and programs to ensure MMD's Quality Compliance excellence including enabling a Quality Management Maturity program within MMD. Prior to joining Merck, Dr. Mehta spent over 10 years at the U.S. FDA in various roles within CDER and the Commissioner's Office where he facilitated the adoption and implementation of the US-EU MRA. He has a PhD in Pharmacology and Molecular Sciences from the Johns Hopkins School of Medicine.



**Melissa J. Mendoza, JD** – Ms. Mendoza is the Director of the Office of Compliance and Biologics Quality (OCBQ) in the Center for Biologics Evaluation and Research (CBER) at the United States Food and Drug Administration. OCBQ oversees CBER-regulated products over their entire lifecycle, from pre-market review and inspection to post-market review, surveillance, inspection, outreach, and compliance. Prior to her current role, Ms. Mendoza served as OCBQ's Deputy Director for six years. Before joining CBER, she worked for eight years in FDA's Office of the Chief Counsel where she was an Associate Chief Counsel for Enforcement.



**Lesley Merkle, BS, BA** – Ms. Merkle is the Associate Director of Compliance for Sanofi and the Site Risk Champion for Framingham Biologics and Biosurgery divisions, where she develops and manages the Quality Risk Management Deployment Strategy. The last 10 years of Ms. Merkle's 21-year career in Quality have been in Quality Risk Management. After graduating from Northern Arizona University with degrees in Biology and English, she worked for the American Red Cross and then Genzyme, which was absorbed into Sanofi.



**Christopher T. Middendorf, BS, MS** – Mr. Middendorf is the VP Technical, Compliance at Parexel and has over 20 years of experience with FDA. He conducted numerous inspections around the globe and was stationed at FDA's Beijing Office for three and a half years. His last position at FDA was Senior Policy Advisor in CDER's Office of Compliance. Prior to joining Parexel, Mr. Middendorf was a Director of Regulatory Affairs and GMP Compliance at Hogan Lovells where his primary responsibility was leading clients through FDA enforcement remediations.



**Peter Millili, PhD** – Dr. Millili started his career working at Merck & Co. in vaccine manufacturing technical operations. In 2014, he joined Bristol-Myers Squibb, working in the large molecule parenteral manufacturing science and technology (MS&T) organization. In 2021, Dr. Millili joined the BMS cell therapy organization, where he served as a site MS&T head, supporting the manufacture of commercial autologous CAR-T therapies. In 2023, he joined Janssen Pharmaceuticals as the global MS&T head for Advanced Therapies. Dr. Millili received his PhD in Chemical Engineering from the University of Delaware.



**Riley Myers, PhD** – Dr. Myers is Chief of FDA's Advanced Pharmaceutical Manufacturing Laboratory and a member of the Office of Pharmaceutical Quality's Emerging Technology Team. He is also a member of the Framework for Regulatory Advanced Manufacturing Evaluation (FRAME) working group where he is evaluating approaches for regulating future distributed manufacturing technologies. He was previously a Lead Biologist in the Office of Biotechnology Products. Dr. Myers received his PhD in immunology from the University of Alabama at Birmingham.

# About the Speakers



**Scott Nichols, PhD** – Dr. Nichols graduated from the University of Iowa with a BS in Biochemistry, continued as a Fulbright Scholar in Microbiology at the Pasteur Institute, and completed his PhD at Johns Hopkins in Molecular Biophysics. He worked as a microbial control and sterility assurance lead reviewer and lead inspector at the FDA for CDER-regulated BLAs and as a consultant for regulatory and compliance issues for biotechnology and cell therapy clients. Dr. Nichols is now Director of Corporate Quality Compliance for Kite Pharma, a leading CAR-T manufacturing company with facilities in the US and EU, responsible for internal quality compliance audits, inspection readiness, regulatory commitments, and post-market reporting.



**Kenneth Pierce, PhD** – Dr. Pierce is the Technical SME Europe, Cleaning Validation & Cleaning Science, at Hyde Engineering + Consulting, Inc. He has 15 years of experience in R&D and pharmaceutical project delivery across multiple areas, including CIP, SIP and process technical SME services, ultra-low temperature and pressure molecular chemistry, inorganic drug development and bio-analytical neurochemistry. With his experience in conceptual design, cleaning process design, development and validation, data analysis, process improvement, sustainability, lifecycle management and quality-by-design, Dr. Pierce leads technical teams in cleaning programs, process improvements, and new product introductions, working cross-functionally for projects in \$X00 million biopharmaceutical facility start-ups and remediation/retro-fit. He is currently engaged with ASTM and ASME developing new industry standards and scientific understanding in the areas of cleaning and equipment design.



**Peter D. Smith, BS** – Mr. Smith, Principal, Smith GMP Consulting, began an independent consulting company upon retiring from PAREXEL in April 2018 after 23+ years. He continues to work with clients in the pharmaceutical and biologics industry worldwide. Mr. Smith joined PAREXEL (then KMI) following a 22-year FDA career. At the FDA, Mr. Smith worked as an Investigator, specializing in pharmaceutical GMP/GCP and medical device inspections and later served as Associate Director, International and Technical Operations Branch, Division of Field Investigations at FDA headquarters, where he managed the Foreign Inspection Program. He is a highly experienced public speaker and trainer in GMP and FDA inspection readiness topics.



**Maggie Snow, BS** – Ms. Snow is the Director of Quality Compliance for Sanofi in Framingham, Massachusetts. She has held multiple positions with increasing responsibility in Manufacturing, Quality Assurance, Quality Systems, and Quality Compliance. Ms. Snow has extensive experience leading transformation teams improving quality systems for global compliance. Her current responsibilities include site Quality Compliance, Risk Management, Internal Auditing and External Inspections. She is a member of BioPhorum Inspections and Quality Network. Ms. Snow has over 25 years' experience and holds a BS in Biochemistry from the University of New Hampshire.

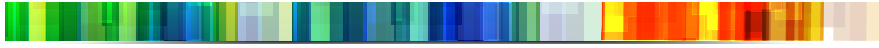


**Joseph T. Varghese, BS, MBA** – Mr. Varghese is the Head of GxP Data Integrity, Global Quality at Bristol-Myers Squibb. He has over 21 years of industry experience, and prior to joining BMS, Mr. Varghese worked at Teva Pharmaceuticals, Merck, and Schering-Plough, where he had extensive experience in compliance, data integrity, data quality, computer systems validation, quality systems development, change management and documentation. He holds a Master's Degree in Business Administration in Management Technology and a Bachelor's of Science in Management Information Systems from New Jersey Institute of Technology, Newark, NJ.



**James Vesper, PhD, MPH** – Dr. Vesper is the Director of Learning Solutions ValSource, Inc. He designs and develops instructional courses and workshops for the pharmaceutical industry. Dr. Vesper previously worked at Eli Lilly, establishing and leading their GMP training organization, and was the founder/president of LearningPlus. As a consultant and trainer, he works globally for a variety of pharma manufacturing firms and has provided training for US FDA, PIC/S, and the World Health Organization. He has written six books and numerous peer-reviewed articles and book chapters on GMP and learning topics.

# Agenda



## Monday, August 14, 2023 Morning Session: Moderator – David Chesney

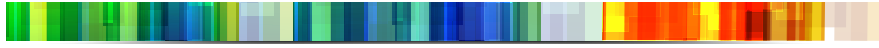
8:00 – 9:00	Registration	
9:00 – 9:10	Welcome*	David Chesney
	Introduction*	Robert Darius
9:10 – 9:45	<b>Keynote: From Pharma Executive to Patient</b>	Michael LaBruto
9:45 – 10:15	<b>Update of FDA Drug Inspection Compliance Programs</b>	Peter Smith
10:15 – 10:35	Break*	
10:35 – 11:05	<b>Center Update: CDER</b>	CDER, FDA (invited)
11:05 – 11:35	<b>Center Update: CBER</b>	Peter Marks, MD, PhD, CBER, FDA
11:35 – 12:05	<b>Center Update: ORA</b>	ORA, FDA (invited)
12:05 – 12:30	<b>Question and Answer Session</b>	Morning Speakers
12:30 – 1:45	Lunch*	

## Afternoon Workshops

1:45 – 3:15	<b>Workshop 1: Oversight of Contract Manufacturers</b> Many companies outsource at least some of their FDA-regulated activities to contract manufacturing organizations (CMOs), such as drug substance and drug product manufacturing, quality control testing, or packaging. Even though GMP-related tasks are delegated to CMOs, the ultimate responsibility for product quality and for ensuring cGMP compliance lies with the application holder. This workshop will address some of the challenges, including technology transfer and routine manufacturing operations, for both application holders and CMOs.	Peter Smith Douglas Farquhar John Hyde
	<b>Workshop 2: Deviations – Turning Failures into Quality and Business Success</b> This workshop provides a highly interactive discussion with FDA drug experts along with industry best practices to turn quality system failures into success. <i>Objectives:</i> <ul style="list-style-type: none"><li>• Explore FDA’s perspective on the most common issues with handling deviations and tips to avoid them.</li><li>• Discuss industry best practices to investigate, prevent, and predict quality system failures.</li><li>• Brainstorm ways to leverage deviations to improve business results.</li></ul>	Industry: Steven A. Greer Regulator: OPQO, ORA, FDA (invited)
	<b>Workshop 3: GMP 101: An Overview of the Drug Product CGMPs</b> Topics will include: <ul style="list-style-type: none"><li>• Historical context of the US CGMPs</li><li>• Characteristics of CGMP-compliant products</li><li>• Seven essentials of GMPs (note: intentionally left out the “C” here)</li><li>• Challenges in meeting the essentials</li></ul>	David Chesney James Vesper, PhD



# Agenda



## **Workshop 4: CGMPs and Aseptic Processing for Cell and Gene Therapy**

Peter Millili, PhD  
Scott Nichols, PhD

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

3:15 – 3:35

Break\*

3:35 – 5:05

**Workshops Session 2 - the above workshops will be repeated**

6:00 – 7:30

Networking Reception\*

## **Tuesday, August 15, 2023**

### **Morning Session: Moderator – Steven A. Greer**

8:30 – 8:35

Announcements\*

8:35 – 9:35

**From Regulator to Regulated –  
Virtual Inspections from A to Z**

Maggie Snow  
ORA, FDA (invited)

9:35 – 10:05

**Realizing Supply Chain Resiliency through a Commitment to Quality**

Jennifer Maguire, PhD, OQS, OPQ,  
CDER, FDA

10:05 – 10:25

Break\*

10:25 – 11:15

**CDER Compliance Update, plus Warning Letters**

Francis Godwin, OMQ, OC, CDER,  
FDA

- APIs and Excipients New/Evolving Area
- ICH Q3D
- No Regulatory Compliance on APIs
- If Want - Open to Plan

11:15 – 11:55

**Panel: Communicating with FDA on GMP Issues**

Speaker:  
OMQ, OC, CDER, FDA (invited)

Panelists:  
Maria Anderson, CBER, FDA  
ORA, FDA (invited)

11:55 – 12:25

**Question and Answer Session**

Morning Speakers

12:25 – 1:40

Lunch\*

## **Afternoon Workshops**

1:40 – 3:10

**Workshop 1: Industry Perspective:  
Implementing a Quality Management Maturity Program**

Alexander Chung, PhD  
Niraj Mehta, PhD

Discuss how industry is preparing ourselves to integrate FDA's Quality Management Maturity program:

- Quality Culture Maturity Attribute Tools/Assessments
- Interpretation of the outcomes from Quality Culture assessments and implementation of actions for continuous improvement
- Utilization of Quality Metrics and an evolution to predictive analytics

# Agenda



## **Workshop 2: Avoiding and Remediating a Warning Letter**

The speakers will lead a discussion on the chain of events set in motion once an FDA 483 is issued and the Agency receives a firm's response and offer insights on developing risk-based remediations and crafting a response that effectively communicates the firm's corrective and preventative actions to FDA. The speakers will also lead a discussion on strategies for remediating enforcement actions.

- 483
- Warning Letter
- Anatomy of a Warning Letter
- Case Study: Manufacturer/Regulatory/CMO

David Elder  
Christopher T. Middendorf  
OMQ, CDER, FDA (invited)

## **Workshop 3: Current Best Preparatory Practices for Regulatory Audits of Cleaning and Contamination Control Practices**

The materials presented in this session will address best practices for regulatory audit preparations for both pre-approval inspections (PAIs) and periodic GMP inspections for critical aspects of process equipment cleaning and cleaning validation activities. *The session will specifically address:*

- Country specific and global cleaning validation requirements and expectations including 21 CFR 211, EurdraLex Vol. 4 Annex 15, ICH Q7, US FDA Cleaning Validation Guidance, Health Canada Cleaning Validation Guidelines, PIC/S PI 006-3 and others
- GAP analysis methodologies for audit preparation
- Best practices for cleaning validation program design and documentation
- Effective organization and presentation of cleaning validation testing methodologies and data to regulatory auditors
- Strategies for response to cleaning related questions from auditors both in real-time during an inspection and follow-up responses to regulatory observations
- Group problem solving from case studies

John Hyde  
Kenneth Pierce, PhD

## **Workshop 4: Phase Appropriate GMPs Considerations**

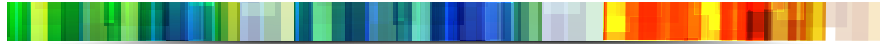
This workshop will present current industry thoughts on how to best implement phase appropriate GMP quality systems, practices and procedures, in alignment with international Health Authority expectations. Key concepts will be drawn from PDA Technical Report TR56 (Application of Phase Appropriate Quality Systems and GMP to the development of Biological API), and other relevant sources.

Some of the topics to be discussed will be:

- Phase Appropriate Quality Systems and GMPs, as implementation of best practices for product development quality
- The interaction between GMP and CMC
- Phase Appropriate CMC and Specification development timeline

David Chesney  
Amnon Eylath

# Agenda



3:10 – 3:30

Break\*

3:30 – 5:00

**Workshops Session 2 - the above workshops will be repeated**

6:00 – 8:00

**Evening Social**

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

**Wednesday, August 16, 2023**

**Morning Session: Moderator – Lynne Ensor, PhD**

8:30 – 9:05

**Data Integrity: An Essential Catalyst on the Quality Management Maturity Journey**

- Computer Software Assurance
- Digital Transformation and AI
- Process and People – Not Just Systems
- Quality and Data Culture
- Better Understanding Behind Procedures
- Street vs. book smart. The Why?

Moderator: Joe Varghese

Panel:

Kir Henrici

OPQ, CDER, FDA (invited)

Al Habib

9:05 – 10:05

**An FDA Perspective on the Future of Pharmaceutical Manufacturing**

Riley Myers, PhD, OBP,

OPQ, CDER, FDA

**AND**

**Preventing Material Shortages Using Monosource and Single Use Technology Risk Assessment**

Lesley Merkle

Monosource risk assessment provides the structure to prioritize and evaluate key manufacturing materials and develop a mitigation strategy to ensure steady supply of materials. This presentation teaches how to zero in on key materials, familiarizes stakeholders with a risk tool and methodology, and provides guidance on how to select a mitigation strategy.

**AND**

**Leading Indicators of Quality through SPC**

10:05 – 10:25

\*Break

10:25 – 10:55

**Office of Enforcement Update**

OEIO, ORA, FDA (invited)

10:55 – 11:25

**CBER Compliance Update**

Melissa Mendoza, CBER, FDA

11:25 – 11:45

**GMP Current Trends (“Coming Around the Corner” Signals)**

Raymond Bonner

11:45 – 12:30

**Ask FDA Q&A Session**

Douglas Farquhar

12:30

**Closing**

FDA Speakers

\*Denotes non-educational activity

Continuing Education



Conference qualifies for 16.0 hours of CE credit.

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# Registration



## 27<sup>TH</sup> ANNUAL GMP BY THE SEA

### Fees



	<b>Industry</b>	<b>U.S. Gov't &amp; Press</b>
<b>EARLY DISCOUNT: Payment Received By June 2, 2023</b>	<input type="checkbox"/> \$2945	<input type="checkbox"/> \$1995
<b>Payment Received After June 2, 2023</b>	<input type="checkbox"/> \$3145	<input type="checkbox"/> \$1995

Includes conference materials, continental breakfasts, breaks, lunches, networking reception, 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.

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- 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.

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### Hotel



#### **Hyatt Regency Chesapeake Bay Hotel**

100 Heron Blvd, Cambridge, MD 21613 | (410) 901-1234

**\$245 single/double**

A limited number of rooms have been blocked at the special rate listed per night. Rate is available 3 nights either side of the conference dates, based upon availability of rooms. **Hotel reservations must be made on or before July 28, 2023, 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.**

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**OR**

**<https://www.hyatt.com/en-US/group-booking/CHESA/G-PMCO>**

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