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28TH ANNUAL

GMP BY THE SEA

AUGUST 12 – 14, 2024 | CAMBRIDGE, MARYLAND

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About the Conference

While the advancements in supporting technology and the current complexity of certain medical products offer exciting opportunities, manufacturers must remain vigilant in adhering to current good manufacturing practices (cGMPs), navigating regulatory complexities, and addressing supply chain constraints to ensure the continued success and sustainability of their operations.

Maintaining consistent availability of quality medical products to patients, especially those in desperate need of them, continues to be an on-going challenge. Recent legislative efforts, particularly by the United States government, aim to alleviate challenges contributing to supply chain shortages.

The U.S. Food and Drug Administration (FDA) has ongoing planning and implementation efforts for significant reorganization and improvements within it to mitigate efficacy, safety, quality and availability challenges, particularly within the Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), and the Office of Regulatory Affairs (ORA). These efforts will impact regulatory review and inspection activities related to cGMPs. Therefore, it is critical to remain informed regarding regulatory expectations to ensure understanding, regulatory assessment and inspection processes, and maintain cGMP during production.

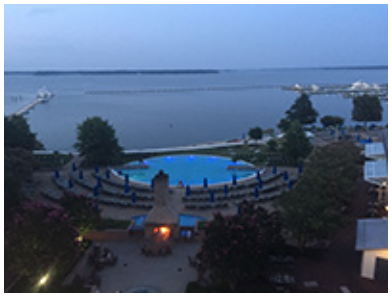
Keynote speakers at the ***GMP By The Sea*** conference will address these various topics and include patient advocate John Lewin, providing insights into the patient perspective, and CDR Emily Thakur from CDER Drug Shortage Staff, presenting updates on the FDA efforts to mitigate patient drug shortages. Representatives from FDA's ORA, CDER, and CBER, including Dr. Peter Marks, Melissa Mendoza, Alonza Cruse, Matt Lash, and Francis Godwin, will share updates on reorganizations, process improvements, compliance, and enforcement activities.

The conference will also address the rapid evolution of the manufacturing environment and tools, including the application of artificial intelligence/machine learning (AI/ML), continuous manufacturing, and emerging technologies. As the use of AI/ML in quality management systems, manufacturing, and regulatory assessment is seen as a promising development, presentations on the implications of AI/ML for GMP will be included at the conference, as well as updates on FDA quality management maturity.

Valuable interactive workshops offered will cover topics such as maintaining GMP compliance, understanding good clinical practice (GCP), preparing for and responding to regulatory inspections, quality risk management, and current cell and gene therapy GMPs.

To close the conference, a final FDA panel will afford attendees the opportunity for an interactive Question & Answer session with regulators.

In addition to being the premier national GMP conference, the ***GMP By The Sea*** conference offers a comprehensive experience that combines education, networking, and professional development opportunities, making it a must-attend event for individuals and organizations involved in the production and regulation of medical products.



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

Attendees have 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!"

"I enjoyed the format, AM large groups and PM breakouts."

"The conference is great with so many FDA speakers."

"Great talk by new faces in discussions like QMM & DI plenary."

"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

To receive emails on our upcoming programs, add reception@pharmaconference.com to your address book.

About the Speakers

Jennifer Ahearn, BS – Ms. Ahearn, CEO of GMPACT, LLC, specializes in pharmaceutical and medical device regulatory compliance. She spent several years with the FDA in numerous roles including bench chemist, domestic and international investigator, technical liaison for FDA's Office of Criminal Investigations, and member of FDA's National Training Cadre, making her an expert in the interpretation and application of cGMP regulations relating to pharmaceutical manufacturing. Ms. Ahearn has assisted pharmaceutical, medical device, combination products, and dietary supplement companies preparing for FDA inspections, as well as responding to FDA 483 observations after an inspection. She has worked to resolve technical and FDA compliance issues for virtually all pharmaceutical dosage forms, medical devices, combination products and dietary supplements.

Ileana Barreto-Pettit, RN, MPH – Ms. Barreto-Pettit is the Vice President – Technical, Strategic Compliance Consulting at Parexel International. She has held several roles in her 24 years of work experience at the U.S. FDA, with her most recent position being Drug National Expert in the Office of Regulatory Affairs. Ms. Barreto-Pettit has conducted hundreds of domestic and international inspections and provided inspectional and technical assistance to field and foreign offices on complex pharmaceutical inspections and regulatory matters. She was an FDA trainer for 17 years, training hundreds of new drug investigators, compliance officers, chemists, microbiologists, and drug application reviewers on the federal drug regulations and inspectional process.

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.

Alonza Cruse, BS – Mr. Cruse is director of the Office of Pharmaceutical Quality Operations within the Office of Regulatory Affairs (ORA) in the Food and Drug Administration (FDA). His office is responsible for all pharmaceutical quality inspections and investigations, working in conjunction with FDA's Center for Drug Evaluation & Research and the Center for Veterinary Medicine. From 2013 to 2015, he served as the acting director of the Office of Medical Products & Tobacco Operations within ORA, overseeing activities such as implementation of the Generic Drug User Fee Amendments, pharmacy compounding, and the development of a new inspection protocols program. Prior to that, Mr. Cruse was the director of the Los Angeles District Office, where his responsibilities included providing executive leadership to implement, manage and evaluate FDA's regulatory operations. Mr. Cruse first joined ORA in 1983 as a microbiologist. He received his Bachelor of Science degree in medical technology from York College (City University of New York).

Michael de la Torre, MBA – Mr. de la Torre, the founder and CEO of Redica Systems, is a data analyst at heart. He is leading the way in applying advanced analytics and AI to regulatory and vendor intelligence. Mr. de la Torre began his career at McKinsey & Company and has held executive roles in Product Management, Marketing, and Business Development. He received his Bachelors in International Finance from Texas A&M University and his MBA from University of Chicago Booth School of Business.

David Doleski, BS – Mr. Doleski is the Compliance Head, Vaccines for Sanofi and is responsible for ensuring inspection readiness and regulatory compliance. He was the Head of Global Quality Audit in Sanofi. Previously, Mr. Doleski served in FDA for over 27 years in leadership positions related to inspection and review programs for drugs and biologics. His last FDA position was Acting Deputy Director for OPF (now OPMA), an office responsible for pre-approval inspections and application reviews.

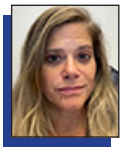
Lynne Ensor, PhD – Dr. Ensor is a consultant to the biopharmaceutical industry, with expertise in sterile product manufacturing, regulatory strategy, and compliance. She recently joined NSF where she is the Senior Director for Pharma Biotech and Dietary Supplements Consulting. Currently, Dr. Ensor is a member of the U.S. Pharmacopeia Microbiology Expert Committee (USP 2020-2025 Council of Experts). During her 21 years at FDA, she served as the Deputy Office Director in the Office of Process and Facilities/Office of Pharmaceutical Quality (OPQ) and on the senior leadership teams in CDER's OPQ and Office of Generic Drugs. Her prior experience includes Parexel International, Roche Biomedical Laboratories, the Discovery Channel, and the University of Maryland's School of Medicine.

Francis Godwin, MBA – Mr. Godwin is Director of the Office of Manufacturing Quality, OC, CDER, FDA. He oversees regulatory and enforcement actions for both foreign and domestic drug CGMP cases. Mr. Godwin received his undergraduate degree from MIT in Chemical Engineering in 2001. After graduation he worked as a process engineer designing, building, and optimizing chemical plants. He was certified as a Black Belt in Six Sigma performing quality improvement projects and teaching Six Sigma principals and worked in pharmaceutical process validation for both batch and continuous processes for APIs and finished dosage manufacturing operations. Later, Mr. Godwin managed an analytical chemistry laboratory conducting analyses for production, QA, and research testing. In 2009 he received an MBA from Georgetown University and since then, has been working at FDA in CDER's Office of Compliance.

Steven A. Greer, BS – Mr. Greer is a Senior GMP consultant for GMPACT. 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" a few 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.

About the Speakers

Jane Halpern, PhD – Dr. Halpern is Executive Director, Regulatory Affairs at IAVI, with a focus on development of vaccines and biologics for HIV and emerging infectious diseases and manages interactions with regulatory agencies in the U.S., Europe, and different African countries. Previously, Dr. Halpern worked at the FDA focusing on research and regulation of bacterial vaccines. She has also worked in biotechnology with positions at ID Biomedical Corporation/GSK Biologics where she managed licensure of an influenza vaccine via accelerated approval. Dr. Halpern received her Ph.D. in Pharmacology and Toxicology from the University of Rochester.



Christine Harman, PhD – Dr. Harman is a CMC/facilities team lead in the Division of Manufacturing and Product Quality (DMPQ), in the Office of Compliance and Biologics Quality (OCBQ)/CBER/FDA. In 2009, she joined CBER in the Office of Blood Research and Review (OBRR) in which she performed regulatory review, in addition to conducting research. Dr. Harman's research area focused on antibody neutralization of the Hepatitis C virus, resulting in several publications including a first author publication. In 2014, she moved to OCBQ in which she is responsible for the review of Investigational New Drug (INDs) applications, Biologics License Applications (BLAs) and manufacturing supplements for a variety of biological products, which include bacterial and viral vaccines, cellular and gene therapies, hematologic recombinants, blood fractionation products, and in-vitro diagnostic kits. In addition to regulatory review activities, Dr. Harman also performs inspections of facilities manufacturing biological products.

Jonathan Helfgott, BS, MS – Mr. Helfgott is the Co-Founder of Healthcare Innovation Catalysts overseeing global clinical research and regulatory activities, including product approvals, submissions, clinical trial design/conduct, inspections, and communications with health authorities and payors. He worked at the FDA from 2006-2015, most recently as the Associate Office Director for Risk Science at CDER, and as a compliance officer and pre-market reviewer at CDRH, specializing in Digital Health and Software in/as a Medical Device (SiMD/SaMD). Mr. Helfgott is a Faculty member/Senior Lecturer for the MS in Regulatory Science graduate program at Johns Hopkins University and is the elected President of AGRE.

John M. Hyde, BS, BBA, MS – Mr. Hyde is a pharmaceutical engineering and regulatory compliance expert with over 40 years of experience designing and qualifying pharmaceutical manufacturing equipment systems for cGMP operations. He is the Founder and Principal at Hyde Emeritus LLC, a consulting firm that provides expert services to pharma and biopharma manufacturers and legal entities, including engineering, and cGMP regulatory consulting and expert witness work. Mr. Hyde also is the Founder and a Senior Principal at Hyde Engineering + Consulting, Inc., a boutique biopharmaceutical engineering firm focusing on process equipment design and integration for cGMP manufacturing facilities. For 11 years prior to the start of Hyde Engineering + Consulting, Inc., he gained significant experience as Process Engineer and Process Engineering Manager at Seiberling Associates, Inc. and as Senior Project Engineer at Synergen, Inc., a biopharmaceutical manufacturing and research firm. Mr. Hyde's regulatory compliance experience includes manufacturing facility pre-inspection auditing and preparation, "back room" support during PAI and routine GMP inspections, and post inspection response report generation and remediation planning. He has specific and in-depth expertise in biopharmaceutical manufacturing systems, cleaning (CIP), and sterilization (SIP).

Matt Lash, JD – Mr. Lash serves as Deputy Director for CDER's Office of Compliance. He joined CDER in 2023 from the Department of Justice, where he served for 13 years as a trial attorney and assistant director. Mr. Lash represented the United States in criminal and civil cases implicating the FDCA and supervised attorneys on many cases related to FDA-regulated products. Before joining the government, he worked at a major law firm. He graduated, cum laude, from Georgetown University Law Center in 2006.

John J. Lewin III, PharmD, MBA, FASHP, FCCM, FNCS – Dr. Lewin is the Chief Medical Officer of On Demand Pharmaceuticals (ODP) where he oversees the quality, regulatory, and pharmacy functions and is working to develop ODPs future distributed and point-of-care manufacturing approach. He is also an associate professor of anesthesiology and critical care medicine at the Johns Hopkins University School of Medicine and maintains a part-time clinical pharmacy practice in the neurosciences critical care unit at The Johns Hopkins Hospital. Prior to joining ODP full-time, Dr. Lewin was the director of the Critical Care & Surgery pharmacy division at Johns Hopkins for 11 years. Prior roles included clinical specialist positions at Johns Hopkins and University of Maryland Shock Trauma Center.

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.

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About the Speakers

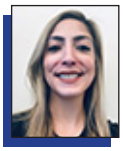
Melissa J. Mendoza, JD – Ms. Mendoza is the Director of the Office of Compliance and Biologics Quality (OCBQ) in the Center for Biologics Evaluation and Research (CBER) at the United States Food and Drug Administration. OCBQ oversees CBER-regulated products over their entire lifecycle, from pre-market 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.

Christopher T. Middendorf, BS, MS – Mr. Middendorf is Vice President Technical, Compliance at Parexel. He has over 20 years of experience with FDA. He conducted numerous inspections around the globe and was stationed at FDA's Beijing Office for 3.5 years. Mr. Middendorf's last position at FDA was Senior Policy Advisor in CDER's Office of Compliance. Prior to joining Parexel, he was a Director of Regulatory Affairs and GMP Compliance at Hogan Lovells, where his primary responsibility was leading clients through FDA enforcement remediations.

Asif Mohammed, MS, MBA – Mr. Mohammed is the founder and CEO of Smart Pharma Solutions, Inc. Prior to starting his journey as an entrepreneur in 2015, he worked in senior Quality and IT leadership positions at Parexel International, Genentech, Roche, and Gilead Sciences. In his current role, Mr. Mohammed routinely serves as an advisor to Chief Quality and Information Officer(s) on their strategic technology initiatives such as developing a cohesive Quality Management Systems and compliance strategy for AI & ML algorithm based clinical Data Management Platforms aimed at accelerating drug discovery, trials and developing Software as Medical Device (SaMD) products, conducts Mock PAI Audits, data integrity assessments, and training.

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 Product Quality for Kite Pharma, a leading CAR-T manufacturing company with facilities in the US and EU and worldwide product distribution. He previously served as the Head of Quality Compliance for Kite, responsible for internal quality compliance audits, inspection readiness, regulatory commitments, and post-market reporting.

William Peterson, BS – Mr. Peterson has spent 14 years dedicated to aseptic processing, specifically sterilizing filtration and sterile connection technology. As an integral member of Merck's Global Quality department, he has established himself as a technical expert within the manufacturing division, supporting dozens of manufacturing sites with respect to selection, validation, and troubleshooting sterilizing filters and sterile connection technologies. Mr. Peterson is actively engaged in multiple industry associations focused on sterile manufacturing, with leadership positions in interest groups related to aseptic processing technologies. He received his B.S. degree in chemical engineering with a concentration in biological engineering from Purdue University.



Viviana Ramirez, MS – Ms. Ramirez is a Gene Therapy Reviewer from the Division of Manufacturing and Product Quality at CBER/FDA. She holds a Master of Science in Biotechnology from North Carolina State University and has been employed by FDA since 2009. She has 15 years of combined experience in facility compliance, drug regulatory affairs (CMC) and multiple aspects of research and development at government.

W. Alex Smith, MBA – Mr. Smith is Director of Regulatory Sciences at Hogan Lovells. As a former software engineer at GlaxoSmithKline and Human Genome Sciences, his primary practice at Hogan Lovells involves assisting companies with medical device and pharmaceutical submissions that involve software such as regulated AI/ML submissions, 21 CFR Part 11 and cyber security concerns. During his time at Hogan Lovells, Mr. Smith has provided software architecture and life cycle advice on a substantial variety of devices such as AI radiological imaging, 3D adaptive manufacturing, Infusion pumps, and individualized vaccines involving AI.

CDR Emily Thakur, BS, RPh – CDR Thakur is a Team Leader with the Drug Shortage Staff at the FDA. She joined the FDA in 1999 as a Consumer Safety Officer for the Regulatory Support Branch in the Office of Generic Drugs. CDR Thakur then joined the Office of Regulatory Policy in the Center for Drug Evaluation and Research in 2005. She has been in her current position, with the Drug Shortage Staff since February 2011. CDR Thakur received her Bachelor of Science degree from Rutgers College of Pharmacy in 1999.

James L. Vesper, PhD, MPH – Dr. Vesper designs and develops instructional courses and workshops for the pharmaceutical industry and currently is Director of Learning Solutions at ValSource, Inc. He previously worked at Eli Lilly establishing and leading their GMP training organization and was the founder/president of LearningPlus. As a consultant and trainer, Dr. Vesper works globally for a variety of pharma firms and has provided training for US FDA, PIC/S, and the World Health Organization. He has authored six books and numerous peer-reviewed articles and book chapters on various GMP and training topics. Dr. Vesper currently is co-lead for PDA's Knowledge Management Task Force and leads the Learning and Training Evaluation Workstream for the Society for Sterility Assurance Professionals.

Agenda

Monday, August 12, 2024
Morning Session: Moderator – Lynne Ensor, PhD

8:00 – 9:00	Registration*	
9:00 – 9:10	Welcome*	Lynne Ensor, PhD
9:10 – 9:45	**Keynote: Patient Advocate**	John J. Lewin III, PharmD
9:45 – 10:15	**Everything You Wanted to Know about Drug Shortages but were Afraid to Ask**	CDR Emily Thakur, CDER, FDA
10:15 – 10:35	Break*	
10:35 – 11:05	**Center Update: ORA**	Alonza Cruse, ORA, FDA
11:05 – 11:35	**Center Update: CDER**	CDER, FDA (invited)
11:35 – 12:05	**Center Update: CBER**	Peter Marks, MD, PhD, CBER, FDA
12:05 – 12:30	**Question and Answer Session**	Morning Speakers
12:30 – 1:45	Lunch*	

Afternoon Workshops

1:45 – 3:15

Workshop 1: Introduction to GCP for GMP Personnel
David L. Chesney, MSJ
Jane Halpern, PhD

This workshop will present an overview of Good Clinical Practice (GCP) regulations and key guidelines in a format specifically targeted to inform GMP QA personnel about the similarities and differences between the GCP and GMP regulations and the role of the Quality Unit in both areas.

Workshop 2: Managing Compliant Manufacturing Capacity
John Hyde
To be determined

Workshop 3: How to Prepare for, Manage During, and Respond Following a Regulatory Inspection
Ileana Barreto-Pettit
Industry: Scott Nichols, PhD

Regulatory Agency and Health Authority inspections are regulatory requirements that protect public health by ensuring that cGMPs are in place at drug manufacturing facilities. In this workshop, we will present points to consider for preparing for and managing health authority inspections before, during, and after the inspection. We will outline and comment on best practices and key resources for site preparation including but not limited to key regulations, ICH Quality documents, FDA guidance documents, and FDA compliance programs guidance manuals. The workshop is intended to be interactive with discussion between presenters and participants.

Workshop 4: Annex 1 Implementation Experiences – Successes & Challenges
William Peterson
Co-facilitator: To be determined

Come prepared to discuss "hot topics" related to the recent Annex 1 revision and its implementation. Case studies will include:

- Appropriate environmental classification for "intrinsic sterile connection devices"
- Critical and non-critical gas filter integrity testing
- Pre-Use, Post-Sterilization Integrity testing of sterilizing filters

Agenda

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 13, 2024
Morning Session: Moderator – Niraj Mehta, PhD

8:30 – 8:35	Announcements*	
8:35 – 9:20	**GMP Implications for Artificial Intelligence and Machine Learning (AI/ML)**	Michael de la Torre
9:20 – 9:55	**Part 11, Automation, and Advanced Technologies, Including Artificial Intelligence/Machine Learning**	Jonathan Helfgott
9:55 – 10:15	Break*	
10:15 – 10:50	**Elements of a Strong GMP Training Program**	James Vesper, PhD
10:50 – 11:25	**Quality Management Maturity**	Alex Viehmann, CDER, FDA
11:25 – 12:00	**Question and Answer Session**	Morning Speakers
12:00 – 1:15	Lunch*	

Afternoon Workshops

1:15 – 2:45

Workshop 1: Application of Artificial Intelligence/Machine Learning (AI/ML) Technologies in Regulated Life Sciences

Michael de la Torre
Asif Mohammed
W. Alex Smith

This workshop will focus on the introduction to fundamentals of AI/ML technology, its application and on the evolving laws and regulations surrounding AI/ML in the life sciences industry. These include use of AI/ML based models in acceleration of Clinical Trial, development of AI/ML based models as Software used for medical purposes (Software as a Medical Device - SaMD). The workshop will also explore ways of being compliant (including validation of technology involved) under a Quality Management System & cover the speakers experience with implementing AI/ML in the software lifecycle as well as receiving approval for AI/ML predetermined change control plans.

Workshop 2: Current Concepts in Cell and Gene Therapy GMP

Scott Nichols, PhD
Viviana Ramirez, DMPQ, OCBQ, CBER, FDA
Christine Harman, PhD, DMPQ, OCBQ, CBER, FDA

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.

Agenda

Workshop 3: QRM (Quality Risk Management) and the 2023 Revision of ICH Q9 – A Review of the Revised Guidance and Its Associated Training Materials, and Implications for the Industry — Jennifer Ahearn

Learn about the focused revisions to ICH Q9 specifically in the areas of subjectivity in risk assessments and management of risks in supply and product availability and how to apply the associated training materials to routine manufacturing.

Workshop 4: Deviations – Turning Failures into Quality and Business Success — Steve Greer, Ileana Barreto-Pettit

This workshop provides a highly interactive discussion with a former FDA drug expert along with industry best practices to turn quality system failures into success.

Objectives:

- Explore former FDA Investigator's perspective on common issues with handling deviations and tips to avoid them
- Discuss industry best practices to investigate, prevent, and predict quality system failures
- Brainstorm ways to leverage deviations to improve business results

2:45 – 3:05 Break*

3:05 – 4:35 **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 14, 2024
Morning Session: Moderator – David Doleski

8:30 – 9:00	**Data Integrity Enforcement Trends**	Francis Godwin, OMQ, CDER, FDA
9:00 – 9:30	**Data Integrity Remediation Strategies**	Chris Middendorf
9:30 – 10:00	**Question and Answer Session**	Morning Speakers
10:00 – 10:20	Break *	
10:20 – 10:50	**CBER Compliance Update**	Melissa Mendoza, CBER, FDA
10:50 – 11:20	**CDER Compliance Update**	Matt Lash, CDER, FDA
11:20 – 11:50	**Office of Enforcement Update**	OEIO, ORA, FDA (invited)
11:50 – 12:30	**Ask FDA Q&A Session**	FDA Speakers
12:30	Closing*	

*Denotes non-educational activity

Continuing Education

Conference qualifies for 15.0 hours of CE credit

Registration

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Fees

	Industry	U.S. Gov't & Press
EARLY DISCOUNT: Payment Received By May 31, 2024	❑ $3195	❑ $1995
Payment Received After May 31, 2024	❑ $3395	❑ $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). 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

- 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

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$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 26, 2024, 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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