AGENDA AS OF 05 SEP 2024

PDA/FDA Joint Regulatory Conference 2024

CGMP: Leading with Quality and Integrity

09-11 September 2024 | Westin Washington, DC Downtown | Washington, DC

SUNDAY, 08 SEPTEMBER

14:00 – 19:00 | Registration Open

15:00 – 18:00 | Speaker Ready Room Open

MONDAY, 09 SEPTEMBER

07:00 – 19:00 | Registration Open

07:00 – 16:15 | Speaker Ready Room Open

07:00 – 08:30 | Continental Breakfast

08:00 – 09:15 | P1: Opening Plenary
Moderator: Janeen Skutnik-Wilkinson, Director, Global Quality, Regulatory Intelligence and External Engagement, *Moderna*

08:00 | Welcome and Opening Remarks from PDA Leadership and Conference Co-Chairs
Anil Sawant, PhD, Chair, *PDA Board of Directors* and Senior VP, *Merck & Co., Inc.*
Glenn E. Wright, MA, President and CEO, *PDA*
Milind Ganjawala, MS, MBA, Co-Chair, *PDA/FDA Joint Regulatory Conference 2024*
Janeen Skutnik-Wilkinson, Co-Chair, *PDA/FDA Joint Regulatory Conference 2024*

08:30 | A Regulatory Perspective on Quality, Integrity, and FDA Modernization
Patrizia Cavazzoni, MD, Director, Center for Drug Evaluation and Research, *FDA*

08:55 | Q&A

09:15 – 10:15 | Networking Break in the Exhibit Area

10:15 – 12:00 | P2: Center Office Updates
Moderator: Milind Ganjawala, MS, MBA, Division Director, DDQ2, OMQ, OC, CDER, *FDA*

The global regulatory landscape is evolving. How will the FDA continue to optimize its strategies and actions to accomplish its mission to safeguard the quality, safety, and effectiveness of medicines for patients, even with current manufacturing and supply challenges? After introductory presentations on current Center activities, your questions will be posed to executive managers from various FDA Centers! In a roundtable format, the conversation will focus on these issues that are often cross-cutting across different centers and relevant to the entire pharmaceutical space.

10:15 | CBER Updates | Peter Marks, MD, PhD, Director, CBER

10:30 | CDER Updates | Douglas Throckmorton, MD, Deputy Director of Regulatory Programs, CDER

10:45 | CVM Updates | Matthew Lucia, DVM, Director, Office of New Animal Drug Evaluation, CVM

11:00 | ORA Updates | Michael Rogers, MS, Associate Commissioner for Regulatory Affairs, ORA

11:15 | Q&A

12:00 – 13:30 | Lunch on Own

13:30 – 15:00 | Concurrent Sessions

A1: CAPA Strategy: Moving from Reactive to Proactive	B1: CGMP Guidance and Policy Updates	C1: Effective Management and Maintenance of Contract Operations
Moderator: Daniel DeCiero, Consumer Safety Officer, OCBQ, CBER, *FDA* When receiving 483 observations, is your company's CAPA strategy to do the bare minimum to fix the issue? Do you wait for quality issues to arise instead of being proactive in finding and fixing them? In this session, industry quality professionals and FDA compliance officers will discuss how to be proactive instead of just reacting to issues and observations as they arise. This session will discuss how to 1) assure CGMP compliance by identifying adverse manufacturing and quality signals before they cause failures, and 2) implement effective and proactive CAPAs in response to both 483 observations and internally identified quality risks.	**Moderator: Paul Z. Balcer,** Program Manager, OMQ, OC, CDER, *FDA* Guidance documents are important tools to provide an insight into FDA regulatory interpretations and stimulate actionable steps to assure quality through robust CGMP compliance. In this session, participants will learn about recent FDA guidance documents that advance public health by promoting improved CGMP compliance and quality.	**Moderator: Marc Glogovsky, MS,** Business Unit Manager - Microbiology, *ValSource* The pharmaceutical industry has continued the marked shift toward reliance on CMOs in recent years. Many companies now obtain most of their drug product supply from CMOs, rather than producing drugs in-house. The selection of a reliable CMO (or ingredient supplier) and establishing a mutual relationship requires strong quality management systems and processes from both parties. This session will address the importance of KM and QRM for evaluating the manufacturing competencies of a CMO/supplier, establishing trust, and developing a sustainable partnership. Elements including tailoring quality agreements, auditing, data integrity/data governance, and lifecycle risk management will be discussed.
13:30 | Strategic CAPAs: Beyond Fixes, Expanding Impact Across Operations **Jonathan Chapman, MS,** Senior Policy Advisor, OC, CDER, *FDA* **13:55 | Quality Insights: Proactive Strategies and Preventive Measures for Continuous Improvement** **Paulien Groll,** Head of Compliance Excellence, *Takeda* **14:20 | Q&A**	**13:30 | CGMP Guidance & Policy Updates** **Tina Kiang, PhD,** Director, OPQ, CDER, *FDA* **13:55 | Pharma CGMP Guidance & Policy Updates** **Tara Gooen Bizjak, MBS,** Director, CDER, *FDA* **14:20 | Q&A with Panelist** **Michael Kerrigan, PhD,** CVM, *FDA*	**13:30 | Applying QRM Principles to Navigate Better Outcomes and Partnerships with Your CMO** **Douglas A. Campbell,** Senior Consultant, *InterPro QRA* **13:55 | Applications in QRM & KM to Build Trust, Improve Performance, & Enhance CMO Partnership** **Martin Lipa, PhD,** Senior Research Fellow, *TU Dublin PRST* **14:20 | Q&A**

15:00 – 16:00 | Networking Break in the Exhibit Area

16:00 – 17:30 | Concurrent Sessions

A2: Data Integrity and CGMP: Leveraging Digital Tools	B2: QRM Integration in New Sterile Manufacturing Facilities	C2: Non-Compliant Inspections and PAI Withhold Decisions: Recent Inspectional Findings
Moderator: Al Kentrup, Executive VP, *CISPAC LLC* Modern digital capabilities provide great potential to improve problem identification, data analysis, data sharing, cross-disciplinary reviews, quality decision-making, and efficiency. This session will explore how CGMPs and DI will be well served by implementing modern digital strategies. Presenters will address the persistent industry DI issues, focusing on how digital tools could prevent DI problems, while also cautioning to ensure all digital systems are suitable for their intended use. Participants will leave with a better understanding of novel applications of digital tools in production and laboratory settings to enhance CGMP compliance, DI, quality, and efficiency.	**Moderator: Mai Huynh, MS,** Supervisory Chemist, CVM, *FDA* Aseptic processing has always been known as one of the highest risk processes. An effective QRM program is essential in aseptic processing facilities, as risk management can be instrumental in identifying and minimizing potential sources of contamination. This session will outline the important aspects of how to initiate and conduct a QRM process for a new aseptic processing facility or process line. Presenters will share case studies and lessons learned in the effective application of QRM principles and tools, including illustrating steps that can be taken to reduce or eliminate hazards in aseptic process design.	**Moderator: Erika Pfeiler, PhD,** Supervisory Microbiologist, OPQ, CDER, *FDA* Patients expect, and rely on, safe and effective drug products, which require high-reliability manufacturing. But what happens when circumstances take a different turn? This group of FDA experts will discuss recent notable inspection findings that led to official action indicated (OAI) decisions and product recalls, as well as PAI withhold decisions. Participants in this session will hear case studies on the real-world implications of poor quality and come away with an appreciation of the foundational role of CGMPs in assuring reliable drug quality and availability.
16:00 | Prioritizing Root Causes and Enhancing DI with Monte Carlo Failure Mode and Effect Analysis **Paul Hanson, PhD,** VP, *Takeda* **16:25 | Leveraging AI in Pharma Manufacturing – DI Compliance** **Shawn Larson, PhD,** ORA, *FDA* **16:50 | Q&A with Panelist** **Kevin D. Wojtas,** Head, Quality Regulatory Compliance, *Takeda*	**16:00 | De-Risking Your Aseptic Process** **Brooke K. Higgins, MS,** Branch Chief, OC, CDER, *FDA* **16:25 | Unlocking the Power of Prevention Controls in QRM to Optimize Aseptic Processing** **Darshana Patel,** Associate Director, *Merck & Co., Inc.* **16:50 | Q&A with Panelists** **Kristen L. Anderson, PhD,** Microbiologist, CVM, *FDA* **Robert J. Ham,** Investigator, OMPTO, ORA, *FDA*	**16:00 | OAI Inspections and Defective Drugs** **Timothy Pohlhaus, PhD,** Senior Policy Advisor, OC, CDER, *FDA* **16:25 | Pre-License and PAI Trends for Biologics** **Madushini Dharmasena, PhD,** CDER, *FDA* **16:50 | Q&A with Panelists** **Irene Abia-Angeh, PharmD, PhD,** Chemist, CVM, *FDA* **Jonathan G. Swoboda, PhD,** CBER, *FDA*

17:30 – 20:30 | Networking Reception

TUESDAY, 10 SEPTEMBER

07:00 – 19:00 | Registration Open

07:00 – 16:45 | Speaker Ready Room Open

07:00 – 08:30 | Continental Breakfast

07:15 – 08:15 | Concurrent Breakfast Sessions

Breakfast 1: Sterility Assurance: The Role of Supply Vendors, Contract Irradiators, and Laboratories	**Breakfast 2: Anchoring QMM to Business Outcomes**	**Breakfast 3: Platform Tech Development, Part 1: GMP & CMC Considerations for Vaccines**	**Breakfast 4: Is That a Particle? Dealing with Particulates in Cell & Gene Therapies**
Moderator: Marc Glogovsky, MS, Business Unit Manager - Microbiology, *ValSource* Sterility combines two processes – irradiation and microbiological assessment. Ancillary products (e.g., gowns and gloves) used in aseptic processing and bio-processing industries must be sterile before use. So how does a drug manufacturer have confidence that these ancillary products meet this requirement? This session will address the standards, activities, controls, logistics, and documentation chain of the processes that deliver sterile products. A panel will also discuss what microbiologists and quality unit personnel can, and should, assess to be confident that these supplies are fit for use.	**Moderator: Patrick J. Lynch, PhD,** Director, OPQ, CDER, *FDA* FDA's Center for Drug Evaluation and Research (CDER) is establishing a Quality Management Maturity (QMM) program to promote the adoption of mature quality management practices that go beyond current GMP requirements. This session will discuss potential advantages of implementing mature quality management practices, assessment of maturity levels, the steps to evolve quality systems, and the impact of QMM practices on business operations and reliability of the drug supply.	**Moderator: Francesco Cicirello, PharmD, MSc,** Senior Director Global BioNTainer Quality Compliance, *BioNTech* Platform technologies are not a new concept per se, however in the last 5-10 years they have come to prominence as an effective way of using prior knowledge to accelerate the introduction of new products especially in the field of RNA medicinal products. Currently, global regulators are supportive of codifying an approach that would allow streamlined marketing approval of new products that fall within the same manufacturing class. Simultaneously, there are industry led efforts to find the best approach to also apply it to the development phase.	**Moderator: Daniel DeCiero,** Consumer Safety Officer, OCBQ, CBER, *FDA* Explore the critical challenge of particulate contamination in cell and gene therapies (ATMPs). This session will delve into identifying, analyzing, and mitigating particulates to ensure product safety and efficacy. Participants will learn about the latest detection technologies, regulatory requirements, and optimizing practices for contamination prevention. Don't miss this session addressing one of the most pressing issues in the development and production of advanced therapies!

07:15 | Industry Perspective **Arthur Dumba,** Director, *The Society for Sterility Assurance Professionals* **07:40 | Q&A with Panelists** **Mike Sadowski,** Lead Scientist, *Baxter* **Barbara Wilimczyk-Macri, MS,** Senior Compliance Officer, OMPTO, ORA, *FDA*	**07:15 | Utilizing QMM Systems to Meet Business Goals** **RJ Doornbos, PharmD,** VP, Quality Operating Systems and Services, *Amgen* **07:40 | Q&A with Panelists** **Magaly Aham, MSc,** SVP, *Takeda* **Alex Viehmann,** Division Director, CDER, *FDA*	**07:15 | Industry Perspective** **Charalampos Koutsoulas, PharmD, PhD,** Director Product Quality, *BioNTech SE* **07:40 | Q&A with Panelists** **Robin Levis, PhD,** Dep. Director, CBER, *FDA* **Christina Meissner, PhD,** Group Manager, *Austrian Agency for Health & Food Safety*	**07:15 | Industry Perspective** **Sarah Bottini,** Associate Director, Supplier Quality Engineer Lead, *BMS* **07:40 | Q&A with Panelists** **Stephen Langille, PhD,** Senior Microbiology Consultant, *ValSource* **John H. Vergara, PhD,** Senior Manager, *BMS*

08:30 – 10:15 \| P3: Compliance Office Updates
Moderator: Andrew Hopkins, PGDip, Director, Operation Quality QA Audit and Compliance, *AbbVie*

Featuring Office of Compliance leaders from the FDA Centers and Office of Regulatory Affairs, this session continues as one of the highlights of the Conference. In a roundtable format, FDA's top leaders in compliance and enforcement will describe their programs, initiatives, and recent actions related to inspections and compliance. Regulatory challenges and FDA's current enforcement strategy for a wide array of medical products will be addressed. This is a great opportunity for participants to understand FDA's thinking and expectations for industry compliance. In addition, there will be ample time to ask questions of FDA's senior leadership.

08:30 \| CBER Compliance Updates \| Melissa J. Mendoza, JD, Director, OCBQ, CBER, *FDA*

08:45 \| CDER Compliance Updates \| Jill Furman, JD, Director, OC, CDER, *FDA*

09:00 \| CVM Compliance Updates \| Cindy Burnsteel, DVM, Dep. Director for Drugs & Devices, CVM

09:15 \| ORA Compliance Updates \| Alonza Cruse, Director, OPQO, ORA

09:30 \| Q&A

10:15 – 11:00 \| Networking Break in the Exhibit Area

11:00 – 12:30 \| Concurrent Sessions

A3: Aging Facilities: Use of Risk Communication to Address Issues & Ensure Sustainable Product Quality	B3: Quality Enabling Behaviors	C3: De-Risking Your Quality Control Laboratory
Moderator: Rebecca Dowd, MS, ORA, *FDA* When it comes to aging facilities, the potential for quality impact-related risks grows over time and may not be readily noticed by those closest to the processes.	**Moderator: Janeen Skutnik-Wilkinson,** Director, *Moderna* Discover how behavior modification principles can drive a quality culture within organizations. This session will include a case study on implementing these techniques and insights from a company	**Moderator: Tara Gooen Bizjak, MBS,** Director, CDER, *FDA* One of the three main objectives of ICH Q10 is to facilitate continual improvement, identify and implement appropriate improvements in product quality, the manufacturing

The risks associated with aging facilities are further compounded when communication streams that enable key stakeholder engagement and decision-making are not fully established. Efforts to stay ahead of aging facility risk require timely communication of information to all relevant parties and decision-makers that are able to implement appropriate action. In this session, participants will hear from industry leaders on successful aging facility communication paths and the related impact on product quality. Case studies will illustrate the benefits of good facility and equipment communication and the pitfalls when communication channels fail.	that successfully adopted behavior modification programs, such as performance reviews, reward systems, and leadership development, to enhance quality. Learn practical strategies to foster quality-focused behaviors in your organization!	process, reduction in variability, innovation, and PQS enhancement. This is intended to increase the ability to fulfill a manufacturer's own quality needs consistently. This session will discuss continual reactive and proactive improvement and use of QRM to identify and prioritize areas of focus of the quality control laboratories. For example, how can we learn from out-of-specification and out-of-trend results and general laboratory errors to improve the overall laboratory system (e.g., equipment, methodology choices, and automation)? Presenters will explore case studies in chemistry and analytical laboratories.
11:00 | Industry Perspective **Nicholas Violand,** Director, Enterprise Regulatory Compliance, *Johnson & Johnson* **11:25 | Aseptic Facility Communication & Assessment** **Paul Palmer, MSc, MBA,** Managing Director/ Pharmaceutical Consultant, *Paul R Palmer Limited* **11:50 | Q&A with Panelist** **Sandra A. Boyd,** Drug National Expert, OMPTO, ORA, *FDA*	**11:00 | Behavioral Changes and Management Strategies: Lessons Learned from Sustainable Procurement** **Jane Zhang,** Co-Founder & Co-CEO, *ETCH Sourcing* **11:25 | Cross-Industry Insights: Leveraging Quality Enabling Behaviors for Success** **Jason Kerr, MBS, MBA,** Senior Manager, *Moderna* **11:50 | Q&A**	**11:00 | Quality Control Laboratory Case Studies** **Andrea Sutter Karpinecz, MS,** VP of Quality Control, *Iovance Biotherapeutics* **11:25 | Risk-Proofing Science with a Mindset of Quality Always** **Aaron R. Goerke, PhD,** Site Quality Head, *Merck & Co., Inc.* **11:50 | Q&A**

12:30 – 14:00 | Lunch on Own

14:00 – 15:30 | Concurrent Sessions

A4: Independence of the Quality Unit **Moderator: Irving Ford, MSc,** VP, Quality, *Adaptimmune* Are you independent or is it just an illusion? The Quality Organization must operate independently and have complete autonomy to make decisions. Often, Quality is guided by the demands of "the organization" and decisions are handed to Quality rather than Quality having the final say. If this is the current culture at your organization or an intruder you are trying to stop in its track in your organization, this session will provide information to guide you in your efforts to change the trajectory with robust preventive tactics. Learn how to finally declare your independence and authority!	**B4: Assuring GMPs Through Implementation of Modern Technologies** **Moderator: Patrick Lynch, PhD,** Director, OPQ, CDER, *FDA* This session will explore recent advances in process modeling for monitoring, control, and validation in GMP. Participants will gain insights into the tech life cycle, focusing on early planning for validation and compliance from development through commercialization and post-marketing. Presenters will share case studies showcasing applications in both small and large molecule processes, highlighting practical implementations and benefits.	**C4: Accelerating Robust Manufacturing with Advanced End-To-End Risk Profiling** **Moderator: Janeen Skutnik-Wilkinson,** Director, *Moderna* Developing a robust fill-finish manufacturing process often requires complex, time-consuming iterations, with no guarantee of finding the lowest-risk, most scalable option. Manual process design and documentation create bottlenecks, hindering safety and automation efforts. This session will highlight a new approach using computer-generated, end-to-end process design, risk assessment, and documentation to streamline operations, reduce errors, and enhance scalability.
14:00 | The Secret to a Quality Unit's Independence **Sean McEwen, MEng,** SVP, QA & EHS, *AbbVie* **14:25 | The Case for Global Quality – Compliance and The Bottom Line** **Marcia Baroni, MBA,** VP Quality, Enterprise GxP Compliance & Systems, *Emergent BioSolutions* **14:50 | Q&A with Panelist** **Tracy Guldan, MA,** Head of Quality Systems, *Civica Rx*	**14:00 | Chemometrics for Process Control** **Chunsheng Cai, PhD,** Chemist, OPQ, CDER, *FDA* **14:25 | Towards Adv. Process Modeling for Monitoring & Control of Integrated & Continuous Purification** **Kevin Brower, PhD,** Global Head of Purification Development, *Sanofi* **14:50 | Q&A with Panelists** **Christina A. Capacci-Daniel, PhD,** CDER, *FDA* **Gang Wang, PhD,** Team Lead (Senior Engineer II), *Moderna*	**14:00 | Fast-Track to Robust Manufacturing: A Case Study on Frame-by-Frame Process Modeling** **Jeff Gensler, MBA,** VP of Quality, *Kindeva Drug Delivery* **14:25 | Quantification of Risk Reduction for Robust Manufacturing: A Case Study Addressing ICH Q9(R1) Requirements** **Sebastian Scheler, MSc,** Managing Director and Chief Methodologist, *Innerspace* **14:50 | Q&A**

15:30 – 16:15 | Networking Break and Passport Drawing in the Exhibit Area

16:15 – 17:45 | Concurrent Sessions

A5: Engaging the Whole Organization in Quality **Moderator: Andrew Hopkins, PGDip,** Director, Operation Quality QA Audit and Compliance, *AbbVie* It's not you, it's me! We have all heard the stories – when companies asked who is responsible for quality, the rest of the organization points to the quality unit. This session will show how this culture can be changed and how the rest of the organization can join this journey, and even lead the process! With insights from FDA and senior industry speakers, participants will leave with a better understanding of how this has and can been done, and the impacts when not done properly.	**B5: Innovations in GMP Compliance: Embracing Digital Tech in GMP Manufacturing** **Moderator: Nicole Deschamps, PhD,** Senior Director, *GSK* Using industry case studies, this session will highlight both the current and potential applications of ML/AI and digital twins in GMP manufacturing facilities. The associated regulatory and quality considerations as well as perspectives on future applications and potential challenges with adoption will also be discussed.	**C5: Improving Auditing Programs: Going Beyond a Checkbox Approach** **Moderator: Denyse D. Baker,** AVP, *Eli Lilly* Auditing is a key tool in ensuring robust quality systems and processes so that patients receive safe and effective medicines. Audits can also be tremendously resource intensive requiring expert personnel and significant travel time. To maximize the return on that investment and best use learnings gained to ensure continuous improvement, audit findings need to be integrated with overall quality systems and quality practices. This session will explore best practices for a GMP audit program including how to incorporate current external expectations into an audit plan, how to link risk registers to audit planning and outcomes, and how to incorporate audit learnings back into quality procedures or practices.
16:15 | Case Study **Cormac Dalton, PhD,** VP of Manufacturing (Europe), *AbbVie* **16:40 | Industry Perspective** **Melissa S. Seymour, MBA,** EVP and CQO, *Eli Lilly* **17:05 | Q&A with Panelist** **Kevin O'Donnell, PhD,** Market Compliance Manager, *HPRA*	**16:15 | AI in Manufacturing** **Scot Lindsey,** SVP, Manufacturing & Quality, *Eli Lilly* **16:40 | Digital Twin Applied to Vaccine Manufacturing** **Sandrine Dessoy,** Science & Tech Innovation Director, *GSK* **17:05 | Q&A with Panelist** **Damodharan Muniyandi, PhD,** CQO – Global Quality & Reg. Affairs, *Sai Life Sciences Ltd*	**16:15 | CMO, Partner, and Internal Audits** **David Doleski,** Compliance Head for Vaccines, *Sanofi* **16:40 | Enhancing QS Through Effective Auditing** **Nidia Acevedo, PhD,** SVP, *Eli Lilly* **17:05 | Q&A with Panelist** **LT Seneca Toms, MS, MSEH, RAC,** National Expert, Drugs, OMPTO, ORA, *FDA*

18:00 – 19:00 | Concurrent Interest Group (IG) Sessions

IG1: Technology Transfer

FDA Co-Facilitator: LT Seneca D. Toms, MS, MSEH, RAC, National Expert, Drugs, OMPTO, ORA, *FDA*

Leaders

- **Mirko Gabriele, PhD,** CEO, *InfiniteVision*
- **Elizabeth Kramer, PhD,** Senior Director, *Eli Lilly*

IG2: Quality Systems

FDA Co-Facilitator: Rebecca E. Dowd, MS, Program Division Director, OPQO3, ORA, *FDA*

Leaders

- **Ghada N. Haddad, PhD,** Executive Director, Global Quality Transformation, *Merck & Co., Inc.*
- **Eva M. Urban, MSc,** Senior Director, Risk Management, *BMS*

IG3: Drug Compounding and Sterile Processing/Parenteral Drug Manufacturing

FDA Co-Facilitators

- **Sarah M. Gauna,** Consumer Safety Officer, OC, CDER, *FDA*
- **Brooke K. Higgins, MS,** Branch Chief, OC, CDER, *FDA*

Drug Compounding IG Leaders

- **Arie Anahory, MS,** Senior Director, Strategy and Customer Excellence, *RCA Inc.*
- **David Short,** CQO, *QuVa Pharma*

Sterile Processing/Parenteral Drug Manufacturing IG Leader: Julian Petersen, Head of Global Business Development Pharma, *groninger & co. gmbh*

IG4: Data Governance, Management, Integrity, and Digitalization

FDA Co-Facilitator: Sandra A. Boyd, Drug National Expert, OMPTO, ORA, *FDA*

Leaders

- **Kir F. Henrici,** Chief Executive Officer, *The Henrici Group*
- **Ulrich Koellisch, PhD,** Partner, *GxP-CC GmbH*

IG5: Quality Risk Management

FDA Co-Facilitator: Paul Z. Balcer, Program Manager, OMQ, OC, CDER, *FDA*

Leaders

- **Amanda McFarland, MS,** Senior Consultant, *ValSource*
- **Malav Parikh, ME,** Director, QRM, Global Quality Compliance and Systems, *Takeda*

IG6: Regulatory Affairs

Leader: Ruhi Ahmed, PhD, RAC, Senior VP, *FLAG Therapeutics, Inc.*

WEDNESDAY, 11 SEPTEMBER

07:00 – 15:00 | Registration Open

07:00 – 11:00 | Speaker Ready Room Open

07:00 – 08:30 | Continental Breakfast

07:15 – 08:15 | Concurrent Breakfast Sessions

Bfast 5: Disaster Recovery Planning: Updating Your Contingency Plan	**Bfast 6: X-Ray Tech**	**Bfast 7: Platform Tech Development, Part 2: GMP & CMC Considerations for Cell & Gene Therapies**	**Bfast 8: Building a Bridge: Leveraging Data Governance Towards the Adoption of Emerging Tech**
Moderator: Tara Gooen Bizjak, MBS, Director, CDER, *FDA* *"By failing to prepare, you're preparing to fail." – Benjamin Franklin* A robust contingency and response plan is crucial for disaster event preparation (e.g., tornado, earthquake, etc.). Recently, a tornado caused severe damage to a sterile facility responsible for manufacturing nearly 50 medicines (equating to approximately 8% of the total U.S. hospital supply). This session will focus on the post-disaster responses, how CGMP operations were restarted, and lessons learned for even better preparation for potential future disaster events.	**Moderator: Mai Huynh, MS,** Supervisory Chemist, ONADE, CVM, *FDA* X-ray tech emerged as an alternative to gamma irradiation. How practical and/or reliable is this tech as compared to other means of sterilization? What are the hurdles when considering transitioning from gamma-ray sterilization modalities to X-ray? Using X-ray facility case studies, experts will demonstrate compliance with FDA GMP and the types of testing (e.g., physicochemical, mechanical, extractable testing, etc.,) performed on products to fulfil filing requirements.	**Moderator: Francesco Cicirello, PharmD, MSc,** Senior Director Global BioNTainer Quality Compliance, *BioNTech* Platform technologies are not a new concept per se, however in the last 5-10 years they have come to prominence as an effective way of using prior knowledge to accelerate the introduction of new products, especially in the field of cell and gene therapies. Currently, global regulators are supportive of codifying an approach that would allow streamlined marketing approval of new products that fall within the same manufacturing class. Simultaneously, there are industry led efforts to find the best approach to also apply it to the development phase.	**Moderator: Nicole Deschamps, PhD,** Senior Director, *GSK* We live in an exciting time! Digital transformation, data science, and the utility of emerging technologies, like AI, are fueling the life science industry towards endless opportunities to better serve patients globally. In a GxP environment, the promise and potential of these innovations share a common essential asset: regulated data. Assuring the integrity of regulated data is a requirement of GxP regulations, leading many organizations to implement formal data governance programs within the QMS. This session will address how, in a rapidly evolving and innovative ecosystem, data governance is mission critical, including establishing principles and measures that can be leveraged to build a bridge towards the compliant adoption of emerging tech.

07:15 | Lessons Learned from Rocky Mount **Bryan Timothy Bassler, PhD,** VP, Sterile Injectable & Biotech Quality Operations Cluster Lead, *Pfizer* **07:40 | Q&A**	**07:15 | Industry Perspective** **Betty Howard, MS, MBA,** Senior Radiation Sterilization Manager, *STERIS AST* **07:35 | CDRH Master File Pilot Program to Address Modality Transition & Shortage** **Ryan Ortega, PhD,** Regulatory Policy Advisor, CDRH, *FDA* **07:55 | Q&A with Panelist** **Irene Abia-Angeh, PharmD, PhD,** Chemist, CVM, *FDA*	**07:15 | Industry Perspective** **Markus Gruell, MSc,** VP Head of Quality, *Autolus Ltd.* **07:40 | Q&A with Panelists** **Kathryn Landes,** VP Global Product Quality, *BioNTech* **Omar Tounekti, PhD, MBA,** Manager, Cell, Gene Therapies and Radiopharmaceuticals Division, *Health Canada*	**07:15 | Paving the Way for Innovation and Compliance Through Data Governance** **Kir F. Henrici,** CEO, *The Henrici Group* **07:40 | Q&A**

08:30 – 10:00 | P4: Current GMP Compliance Trends and Topics
Moderator: Ingrid Markovic, PhD, Senior Science Advisor, ORO, CBER, *FDA*

With presentations from CDER and CBER, this can't miss session will provide more than just the "top ten" 483 observations! Experts will highlight recent trends from violative inspections to enforcement actions giving participants key topics to consider and take back to their team members and colleagues for discussion.

08:30 | CDER Updates | Francis RW Godwin, MBA, Office Director, OMQ, OC, CDER, *FDA*

08:55 | CBER Updates | Daniel DeCiero, Consumer Safety Officer, OCBQ, CBER, *FDA*

09:20 | Q&A with Panelists
Marea K. Banks, Consumer Safety Officer, OSC, CVM, *FDA*
Ronda R. Loyd-Jones, MBA, Director, Compliance Branch, OPQO, OMPTO, ORA, *FDA*

10:00 – 10:30 | Networking Break

10:30 – 12:00 | P5: Operationalizing Quality Risk Management and Knowledge Management
Moderator: Paul Z. Balcer, Program Manager, OMQ, OC, CDER, *FDA*

This plenary session will provide practical insight into how QRM and knowledge management (KM) are being operationalized in pharmaceutical manufacturing. International regulators and industry experts will present principles and tangible examples illustrating how QRM and KM optimize manufacturing processes, reduce errors, and ensure compliance with regulatory standards, ultimately safeguarding patient health and trust in quality of medicines.

10:30 | Operationalizing QRM | Kevin O'Donnell, PhD, Market Compliance Manager, *HPRA*

10:55 | Operationalizing KM | Martin Lipa, PhD, Senior Research Fellow, *TU Dublin PRST*

11:20 | Q&A

12:15 – 13:15 | Lunch with the Regulators
Moderator: **Rebecca E. Dowd, MS,** Program Division Director, OPQO3, ORA, *FDA*

In this lunch Q&A session, FDA investigators, reviewers, and compliance officers will answer participants' questions and provide further insights into inspection trends and center initiatives.

Panelists
Sandra A. Boyd, Drug National Expert, OMPTO, ORA, *FDA*
Alifiya H. Ghadiali, PhD, RAC, Lead Consumer Safety Officer, OCBQ, CBER, *FDA*
Brooke K. Higgins, MS, Branch Chief, OC, CDER, *FDA*
Laura S. Huffman, MS, CVM Pre-Approval Facilities Assessment Program, Lead, ONADE, CVM, *FDA*
Derek S. Smith, PhD, Deputy Director, OPMA, OPQ, CDER, *FDA*

13:30 – 14:30 | P6: Closing Plenary
Moderator: **Mary Farbman, PhD,** Associate VP, Global Quality Compliance, *Merck & Co., Inc.*

13:30 | The Evolving Landscape of Pharma Manufacturing | Peter Marks, MD, PhD, Director, CBER

13:55 | Q&A

14:20 | Closing Remarks from the Conference Co-Chairs