FDA/PQRI WORKSHOP ON THE REGULATORY FRAMEWORK FOR DISTRIBUTED AND POINT-OF-CARE PHARMACEUTICAL MANUFACTURING

Biographies

Day 1 – November 14, 2022

Welcome to Conference and PQRI Overview and Introductory Remarks	
Glenn E. Wright Chief Operating Officer Parenteral Drug Association (PDA) wright@pda.org 	**Glenn Wright** currently serves of the Chairman of the Board at PQRI and as the Chief Operating Office at PDA. Glenn has more than 30 years of experience in the pharmaceutical industry. Serving in various technical and senior leadership positions at Eli Lilly, Amgen, and Pfizer. He has extensive technical, regulatory, and quality expertise in both small molecule and biologic drug substance manufacturing as well as sterile injectable drug product manufacturing. Glenn has served on the PDA Board of Directors, Science Advisory Board, and Program Advisory Board. In addition, he has chaired numerous industry meetings, Task Forces, and Steering Committees. Glenn is a frequent speaker at industry events. He received his BS and MS degrees in Microbiology from Southern Illinois University.
A Regulatory Perspective on Innovations in Pharmaceutical Manufacturing	
Michael Kopcha, Ph.D., R.Ph. Director, Office of Pharmaceutical Quality (OPQ), Center for Drug Evaluation & Research (CDER) Food & Drug Administration Michael.Kopcha@fda.hhs.gov 	**Michael Kopcha**, Ph.D., R.Ph. is the Director of the FDA's Office of Pharmaceutical Quality (OPQ). This office has over 1,300 staff responsible for assuring the availability of quality medicines for the American public through assessment, inspection, surveillance, research, and policy. OPQ contributes to the assessment of nearly every type of human drug marketing application including New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), and Biologics License Applications (BLAs), including 351(k) applications (i.e., biosimilars). OPQ also performs the quality assessment of Investigational New Drug Applications (INDs) and establishes quality standards for over-the-counter drug products and facilities. Prior to joining the FDA, Dr. Kopcha amassed more than 25 years of experience in major and mid-sized innovator, generic, drug/device, and over-the counter (OTC) pharmaceutical and consumer health companies. He developed expertise in areas including formulation and process development, product scale-up, process validation, technology transfer, project management, change management, and off-shoring/outsourcing. Dr. Kopcha most recently served as Vice President, and global research and development franchise head, for cough, cold, and respiratory products at Novartis Consumer Health, Inc. Dr. Kopcha earned his doctorate and master's degrees in pharmaceutical science, and a bachelor's degree in pharmacy from Rutgers University. He also served as an adjunct assistant professor in the Department of Pharmaceutics at Ernest Mario School of Pharmacy at Rutgers.

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SESSION 1: Harmonizing Terminology Among All Stakeholders

Moderator:

Adam Fisher, Ph.D.
Director, Science Staff
OPQ/CDER/FDA
adam.fisher@fda.hhs.gov

Adam Fisher, Ph.D. is the Director, Science Staff in the Office of Pharmaceutical Quality (OPQ) in the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration. In this position, Dr. Fisher focuses on engaging FDA stakeholders and supporting advanced manufacturing technologies. At the FDA, he has served in positions of increasing responsibility: a primary and secondary reviewer of Abbreviated New Drug Applications and Drug Master Files, a Team Lead, a subject matter expert on complex drug substances and advanced biomanufacturing, and a liaison to the United States Pharmacopeia BIO1 Expert Committee. He joined the FDA in 2014 as a chemical engineer with expertise in the synthesis of biomolecules.

Dr. Fisher's work prior to joining the FDA focused on the microbial production of proteins and glycoproteins for a host of applications. His Ph.D. dissertation concentrated on the use of the secretion pathways of bacteria to perform protein engineering. Prior to the FDA, Dr. Fisher was the co-founder and Chief Science Officer of a startup company focused on microbial technologies for the production of glycoproteins. He earned his B.S. degree at the University of Maryland College Park (Chemical Engineering) and his Ph.D. at Cornell University (Chemical & Biomolecular Engineering).

Speakers:

Riley Myers, Ph.D.
Lead Biologist
Office of Biotechnology Products
riley.myers@fda.hhs.gov

Riley Myers is a member of the Emerging Technology Team in the Office of Pharmaceutical Quality and a Team Lead in the Office of Biotechnology Products in the Center for Drug Evaluation and Research (CDER) at FDA. He serves as a project lead for technologies accepted into the Emerging Technology Program where he assembles Agency-wide, multidisciplinary teams to provide feedback to applicants developing these technologies. Dr. Myers is also a member of the Framework for Regulatory Advanced Manufacturing Evaluation (FRAME) working group where he is evaluating future approaches for regulating mobile manufacturing technologies. He was previously a microbiologist in the Center for Devices and Radiological Health prior to CDER where he assessed medical devices that contain antimicrobial agents as well as sterilization devices. Before joining FDA, Dr. Myers studied mechanisms to program anti-pathogenic immune responses at Boston Children's Hospital. His scientific expertise is in B cell and dendritic cell biology and their role in regulating humoral immunity. Dr. Myers received his Ph.D. in immunology from the University of Alabama at Birmingham.

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Thomas O'Connor, Ph.D.
Deputy Director, Office of Testing and Research (OTR)/OPQ/CDER/FDA
Thomas.oconnor@fda.hhs.gov


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Thomas O'Connor, PhD is the deputy director of the Office of Testing and Research in the Office of Pharmaceutical Quality and is the vice-chair of CDER's Emerging Technology Team (ETT). His responsibilities include managing research and testing projects that answer and anticipate pharmaceutical quality-related regulatory challenges through scientific approaches. The impact of OTR research and testing is utilized to support regulatory assessment and policy development in areas such advanced manufacturing, drug quality standards, characterization of complex drug substances and drug products, and post market product quality and public health issues. Tom is a co-author of several papers on emerging pharmaceutical technology such as continuous manufacturing, 3D printing, and the utilization of modeling and simulation for quality assurance. Through the ETT he has contributed to the review of several regulatory applications utilizing novel technologies. He is the co-chair of the OPQ Manufacturing Science and Innovation Center of Excellence and is a member of the advanced manufacturing working groups within the FDA. Tom has been at the FDA since 2013 serving in various roles including as a chemistry reviewer in the Office Generic Drugs and a team leader in the immediate office of the Office of Pharmaceutical Quality. Prior to joining the FDA, Tom worked at ExxonMobil Research and Engineering where he held job functions in both process analytical technology and process control. Tom earned a B.S. in chemical engineering from the Cooper Union and a Ph.D. in chemical engineering from Princeton University.
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Panelist:

Carolyn Yong, Ph.D.
Associate Director of Policy, Office of Tissues and Advanced Therapies (OTAT), Center for Biologics Evaluation and Research (CBER)/FDA
carolyn.yong@fda.hhs.gov


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Carolyn Yong serves as an Associate Director of Policy in the Office of Tissues and Advanced Therapies (OTAT) in the Center for Biologics Evaluation and Research (CBER) at FDA. She leads policy, FDA guidance document and regulation development, as well as jurisdiction for OTAT. Dr. Yong liaises with other FDA Centers and external stakeholders, particularly in the advancing fields of biomanufacturing and regenerative medicine. Dr. Yong is also a member of the CBER Advanced Technologies Team and is engaged in both FDA and standards organization activities related to CBER-regulated products. Prior to her current role, she was a Team Leader in the Division of Cellular and Gene Therapies (DCGT) where she conducted scientific regulatory review while providing oversight of DCGT programs related to regenerative medicine applications and combination products. Before joining CBER/OTAT, Dr. Yong served as a Lead Scientific Reviewer in the Center for Devices and Radiological Health (CDRH) for plastics and reconstructive surgical devices. Dr. Yong was previously a Regenerative Medicine Commissioner's Fellow (Class of 2012). Dr. Yong received her Ph.D. in bioengineering and biotechnology from the École Polytechnique Fédérale de Lausanne (EPFL), Switzerland.
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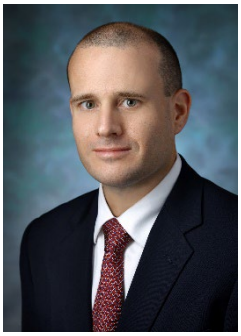
SESSION 2: Operating/Business Models between DM/POC Applicants and DM/POC Sites

Moderator:
Cat Vicente
Associate Director, Enterprise Regulatory Outreach, Johnson & Johnson
CVicent3@its.jnj.com

Catherine Vicente (Cat) has over 17 years' experience in various roles and functions throughout the pharmaceutical industry, ranging from both roles in the laboratory as well as roles within quality & compliance in the Consumer Segment. Cat currently works as Associate Director for the Johnson & Johnson Regulatory Compliance group called Enterprise Regulatory Outreach (ERO), where Cat specializes in regulatory intelligence detection, analysis and communication, as well as analytical laboratory & compendial compliance topics.

Speakers:

John J. Lewin III, PharmD, MBA, BCCCP, FASHP, FCCM, FNCS
Chief Medical Officer
On Demand Pharmaceuticals, Inc.



Dr. John Lewin is the Chief Medical Officer of On Demand Pharmaceuticals (ODP) where he oversees the quality, regulatory, manufacturing and GMP engineering functions and is developing ODPs future distributed and point-of-care manufacturing approach.

Dr. Lewin is also an associate professor of anesthesiology& 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

Dr. Lewin earned his PharmD degree from the Temple University School of Pharmacy, his MBA from the Johns Hopkins University Carey School of Business, and completed a PGY1 and PGY2 critical care residency at the Medical University of South Carolina. He has over 19 years of critical care pharmacy experience, with a primary focus on neurological critical care, and is a board-certified critical care pharmacy specialist. He is an author on over 55 peer-reviewed scientific articles and book chapters, and has delivered over 75 invited presentations at local, national, or international conferences. He is a past-president of the Maryland Society of Health-System Pharmacists, and has been recognized as a Fellow of the American Society of Health-System Pharmacists, the American College of Critical Care Medicine and the Neurocritical Care Society. He is a previous member of the board of directors and executive committee for the Neurocritical Care Society.

Alvaro Goyanes, Ph.D. Co-Founder and CEO, FabRx; Honorary Lecturer, UCL School of Pharmacy a.goyanes@ucl.ac.uk	
Panelist: **Joel Welch**, Ph.D. Chair, Emerging Technology Program, Associate Director for Science & Biosimilar Strategy Office of Biotechnology Products/OPQ/CDER/ FDA *(Invited)*	