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

Biographies

Day 3 – November 16, 2022

SESSION 5: Strategies to Ensure that Drugs and Biologics Meet Established Specifications

Moderator:

Diane Paskiet, MS
Director of Scientific Affairs
West Pharmaceutical Services
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Diane Paskiet has over twenty-five years of experience in the pharmaceutical industry. She is currently Director of Scientific Affairs at West Pharmaceutical Services where she is involved in science and regulatory programs associated with safety and compatibility of pharmaceutical packaging and delivery systems. Previous to this role she was in charge of site operations for West-Monarch Analytical Laboratories. She is on the Product Quality Research Institute (PQRI) Steering Committee and Chair of the Extractables and Leachables Parenteral Drug Product Working Group. Diane is also on the faculty of the Parenteral Drug Association Training Institute and a Board Member of Xavier Health Innovation Training Center of Excellence (ITCE). She has author/co-author a number of papers and book chapters related to pharmaceutical packaging, delivery systems and combination products.

Speakers:

J. Christopher Love, Ph.D.
Professor, Massachusetts Institute of Technology (MIT)
Chairman Sunflower Therapeutics
clove@mit.edu

J. Christopher Love is the Raymond A. (1921) and Helen E. St. Laurent Professor of Chemical Engineering and member of the Koch Institute for Integrative Cancer Research at MIT. His research focuses on advancing next-generation approaches for accessible and affordable biomanufacturing and on single-cell analyses in chronic diseases like cancer and food allergy. He served as a Distinguished Engineer in Residence at Biogen in 2015 and is the founding director of the Alternative Host Research Consortium at MIT. He has also co-founded four companies for biopharmaceutical services and technologies, including Honeycomb Bio, OneCyte Bio, and Sunflower Therapeutics.

Thomas D. Roper, Ph.D.
Professor, Department of Chemical and Life Sciences Engineering, School of Engineering, Virginia Commonwealth University
tdroper@vcu.edu

Thomas Roper is a professor in the Chemical and Life Science Engineering Department at VCU and Director of Pharmaceutical Engineering. His team's expertise is in the development of novel syntheses and continuous processes including PAT implementation, as well as empirical and dynamic modeling. Currently the Roper lab is responsible for working within the Medicines for All team to develop continuous manufacturing processes for pharmaceuticals. Dr. Roper was the PI for the technology transfer portion of the Pharmacy on Demand (PoD) project (post MIT) where his team successfully modified the previous process to ensure production of ciprofloxacin to meet regulatory standards for purity. Prior to this Dr. Roper had a lengthy career at GlaxoSmithKline Pharmaceuticals (GSK) where he held a number of scientific and organizational leadership positions including the Global Head of Exploratory Development Sciences and also as Head of API Chemistry and Analysis for the US. In this position he was responsible for the development of chemistry and analysis for the entirety of the US based small molecule portfolio including clinical supply, process development and transfer to manufacturing.

SESSION 6: DM/POC Suitability for Center for Biologics Evaluation and Research (CBER) Regulated Products

Moderator:

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

Laura M. Ricles, Ph.D.
Chief, Tissue Engineering Branch, Division of Cellular and Gene Therapies (DCGT), Office of Tissues and Advanced Therapies (OTAT), CBER/FDA

Laura Ricles, PhD, is Chief of the Tissue Engineering Branch in the Office of Tissues and Advanced Therapies (OTAT) in the Center for Biologics Evaluation and Research (CBER) at the US Food and Drug Administration (FDA). Dr. Ricles joined the FDA in 2014 as a Commissioner's Fellow and evaluated the scientific trends and regulatory challenges to enhance FDA's review of 3D printed medical products. In 2016, she joined OTAT as a product reviewer and performed chemistry, manufacturing, and controls review of cell therapy products, including stem cell and somatic cell therapies, tissue engineered products, cell-device combination products, and devices, for clinical trial applications and marketing. In 2018, she became Cell Therapy Team Lead in the Cell Therapies Branch in OTAT before becoming Chief of the Tissue Engineering Branch in 2021. She actively participates in working groups and other initiatives at the FDA in the area of tissue engineering, regenerative medicine, and advanced manufacturing. Dr. Ricles earned a B.S. in bioengineering at Lehigh University and a Ph.D. in biomedical engineering at The University of Texas at Austin, where she investigated the use of bone marrow derived mesenchymal stem cell therapy, in combination with 3D biomaterials, for ischemic diseases using in vitro and in vivo models.

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Biographies (Day 3) November 16, 2022

Laura Sands, MSc. Head of Regulatory Affairs, Bioscience and Personalized Medicine, Lonza laura.sands@lonza.com 	**Laura Sands** has over twenty years of experience in the pharmaceutical industry. She is the Head of Regulatory Affairs for Lonza's Bioscience and Personalized Medicine business units providing regulatory support for Lonza's Cocoon® Platform and Bioscience products. Prior to this role, Laura was the Head of Quality Control at Lonza's Cell and Gene Therapy manufacturing facility in Houston, TX. Laura completed her Masters of Science degree in Biotechnology from Johns Hopkins University and holds a Bachelor of Science in Biochemistry and Molecular Biology from the University of Maryland Baltimore County.
Richard McFarland, Ph.D. MD Chief Regulatory Officer Advanced Regenerative Manufacturing Institute (ARMI) rmcfarland@armiusa.org	**Richard McFarland** is an immunopathologist and the Chief Regulatory Officer at the Advanced Regenerative Manufacturing Institute (ARMI) where he over the regulatory affairs for ARMI and its BioFabUSA program. Dr. McFarland is also a Principal Consultant at BioFabConsulting where he consults with members on product classification, regulatory strategy, and CMC, preclinical and clinical studies. Prior to joining ARMI as its first post-award hire in 2017, Dr. McFarland was Associate Director for Policy (ADP) of the Office of Tissues and Advanced Therapies (and its predecessor office) at the Food and Drug Administration's Center for Biologics Evaluation and Research (FDA/CBER) for eleven years after six years a reviewer in FDA/CBER. In addition he, served on the federal government's interagency for tissue engineering and regenerative medicine, the Multi-agency Tissue Engineering Sciences group (MATES) for fifteen years, including five years as its Chair. Dr. McFarland received his undergraduate, graduate, and medical school training at the University of North Carolina-Chapel and his post-graduate medical specialty training in anatomic/clinical pathology and subspeciality training in immunopathology at University of Texas Southwestern Medical Center in Dallas.
Panelist: **Steven S. Oh, ,** Ph.D. Deputy Director, Division of Cellular and Gene Therapies, Office of Tissues and Advanced Therapies (OTAT), CBER/FDA Steven.Oh@fda.hhs.gov 	**Dr. Steven Oh** is Deputy Director of Division of Cellular and Gene Therapies in CBER, FDA. He oversees product quality review and regulatory activities of cell and gene therapy products, tissue-engineered products, and related medical devices used at the point-of-care. He is also involved in developing regulatory policies related to emerging advanced technologies, standards development and use, and global regulatory convergence in cell and gene therapies. He was trained as a cell biologist and biochemist at Massachusetts Institute of Technology, Johns Hopkins University School of Medicine, and the University of Michigan.