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Advances in Therapeutic Development Across Modalities

Panel Discussion: Common Challenges in Bioanalytical Assay Validation/Development in CGTP

Monday, April 24, 2023 2:30 PM – 3:15 PM ET

Location: Learning Lab, Franklin Hall

Partner Presentation Speaker(s)

CV

Carrie A. Vyhlidal, PhD (she/her/hers)

Associate Director
KCAS Bioanalytical and Biomarker Services
Olathe, Kansas, United States

Stephanie A. Pasas-Farmer, PhD (she/her/hers)

President and Principal Consultant
spfarmer@bdatasolutions.com
Lawrence, Kansas, United States

Lillian Falese, MS

Director
Spirovant Sciences, Inc.
Philadelphia, Pennsylvania, United States

Kelly Colletti, PhD (she/her/hers)

Director, Preclinical Bioanalytics
Beam Therapeutics
Cambridge, Massachusetts, United States

DK

David Kuhel, M.S.

Senior Research Scientist
PPD Biomarkers
Highland Heights, Kentucky, United States

Brian D. Bower, PhD

Scientist III, Gene and Cell Therapy
BioAgilytix Labs
Durham, North Carolina, United States

Description: The advancement of cells and gene therapies has called upon the use of existing molecular testing platforms, such as qPCR, ddPCR, and NGS, that are critical to quantifying key end points, such as gDNA, mRNA, %editing, etc. With the use of case studies, this panel will discuss challenges and possible solutions to transition of assays from CLIA to FDA laboratories, acceptance criteria for qPCR and RT-qPCR, and selection of positive controls and housekeeping genes.

Learning Objectives:

- Upon completion, participants will be able to better conduct institutional transitions from CLIA to FDA – molecular platform, assay platform transition challenges and areas of synergy
- Demonstrate how the lack of harmonization around acceptance criteria for qPCR and RT-qPCR can be addressed (consensus is difficult to reach, but an AAPS committee is working toward it)
- Discuss possible solutions around the use of wide spectrum of potential positive controls and housekeeping gene that lead to the lack of harmonization across the industry