ADVANCED MANUFACTURING AND ANALYTIC TECHNOLOGIES (AMAT) IN REGENERATIVE MEDICINE THERAPIES (RMT) WORKSHOP

Tuesday March 14, 2023

AGENDA

9:00 am – 9:10 am **OPENING REMARKS – Steven Oh, Ph.D.**

CELLULAR THERAPY SESSION*

This session also includes discussions of genetically modified CAR T cells

9:10 am – 9:55 am **KEYNOTE ADDRESS:** *Enabling Quality-by-Design (QbD)-driven Manufacturing of Cell Therapies: The Role of Data Science, In/At-line Process Analytics, and Feedback-controlled Automation;* **Krishnendu Roy**, Ph.D.; Georgia Institute of Technology (Atlanta, GA) ***(40 min + 5 min Q&A)***

9:55 am – 11:10 am **PRESENTATIONS**

i. *Manufacturing Mesenchymal Stromal Cells-small Extracellular Vesicles (MSC-sEVs) for Clinical Testing;* **Sai Kiang Lim**, Ph.D.; National University of Singapore; Agency for Science, Technology and Research (A*Star) (Singapore) ***(20 min + 5 min Q&A)***

ii. *Scaling Manufacture of Pluripotent Stem Cell-Based Therapies for Advanced Clinical Development and Eventual Commercialization: Case Study of Development of an Implant for the Treatment of Geographic Atrophy;* **Jane Lebkowski**, Ph.D.; Regenerative Patch Technologies (Portola Valley, CA) ***(20 min + 5 min Q&A)***

iii. *Digital Tools and Adaptive Manufacturing Strategies for Advanced Therapies;* **Qasim A. Rafiq,** Ph.D.; University College London (London, U.K.) ***(20 min + 5 min Q&A)***

11:10 am – 11:20 am **MORNING BREAK**

11:20 am – 12:35 pm

TISSUE ENGINEERING SESSION

PRESENTATIONS

i. *Tissue Engineered Medical Products for Nervous System Reconstruction*; **D Kacy Cullen,** Ph.D.; University of Pennsylvania (Philadelphia, PA) ***(20 min + 5 min Q&A)***

ii. *3D-Printed Biodegradable Scaffolds for the Treatment of Critical-Sized Midfacial Bone Injuries;* **Warren Grayson**, Ph.D.; Johns Hopkins University (Baltimore, MD) ***(20 min + 5 min Q&A)***

iii. *Advanced 3D/4D Bioprinting and Nanotechnology for Complex Tissue Regeneration;* **Lijie Grace Zhang**, Ph.D.; George Washington University (Washington, DC) ***(20 min + 5 min Q&A)***

12:35 pm – 1:05 pm **CELLULAR THERAPY AND TISSUE ENGINEERING PANEL DISCUSSION**
Krishnendu Roy; Sai Kiang Lim; Jane Lebkowski; Qasim Rafiq; D Kacy Cullen; Warren Grayson; Lijie Grace Zhang

1:05 pm – 1:55 pm **LUNCH BREAK**

GENE THERAPY: VIRAL VECTORS SESSION

1:55 pm – 2:40 pm **KEYNOTE ADDRESS:** *AAV Vector Production, Evolution of a Process;* **Jude Samulski**, Ph.D.; University of North Carolina (Chapel Hill, NC) ***(40 min + 5 min Q&A)***

2:40 pm – 3:55 pm **PRESENTATIONS**

i. *Overcoming AAV CMC challenges through the use of platform-based approaches to streamline AAV-based drug development;* **Steven Gray**, Ph.D.; University of Texas Southwestern Medical Center (Dallas, TX) ***(20 min + 5 min Q&A)***

ii. *Directed Evolution of EnhaAAV Delivery Systems for Clinical Gene Therapy*; **David V. Schaffer**, Ph.D.; University of California, Berkeley (Berkeley, CA) ***(20 min + 5 min Q&A)***

iii. *Gene Therapy for Prevalent Diseases: Strategies to improve AAV titer and quality;* **Ali Aghajanirefah**, Ph.D.; Adverum Biotechnologies Inc (San Francisco, CA) ***(20 min + 5 min Q&A)***

3:55 pm – 4:25 pm **GENE THERAPY: VIRAL VECTORS PANEL DISCUSSION**
Jude Samulski, Steven Gray, David V. Schaffer, Ali Aghajanirefah

4:25 pm – 4:30 pm **CLOSING REMARKS**