USP-APEC Center of Excellence for Advanced Therapies
Virtual Training Workshop on "Chemistry, Manufacturing, and Control Challenges in CAR T Cell Therapy"

May 9th and 11th, 2023 (Asia) / May 8th and 10th, 2023 (Americas)

Event Objectives and Agenda

Chimeric antigen receptor (CAR) T cell products are groundbreaking advanced therapies that are revolutionizing personalized medicine. Their novelty, complex development, and manufacturing processes can challenge regulatory agencies. Agencies may need to adapt their regulatory processes and improve their understanding of advanced therapies to support the review of CAR T therapy submissions. To face this challenge, USP in collaboration with the Regulatory Harmonization Steering Committee and Advanced Therapy Priority Work Area champions has built a virtual training program for regulators.

Upon completion of this 6-hour training program, participants will be able to:

1. Describe the principles of CAR T cell therapy and basic regulatory considerations
2. Define key terms and acronyms related to advanced therapies
3. Explain the CMC best practices and concerns that have been seen in regulatory submissions
4. List common critical quality attributes (CQA) and associated analytical methods
5. Discuss common safety and quality challenges faced by CAR T cell manufacturers

The training will include pre-reads and pre-assessments for participants, opportunities to ask questions of the instructors, and a post-assessment to ensure that the training was effective.

DAY 1: Tuesday, May 9, 2023 (Asia); *(Monday, May 8, 2023 (Americas))*	
TIME (SGT/EST)	**PRESENTATION**
8:00 – 8:10 AM SGT *(8:00 – 8:10 PM EST)*	**Introduction: Welcome and Objectives for the Program** Maura Kibbey, Ph.D., Director, Biologics Marketing, USP
8:10 – 8:15 AM SGT *(8:10 – 8:15 PM EST)*	**Welcome from Moderators for Day 1** Jared Auclair, Ph.D., Vice Provost Research Economic Development and Director of Bioinnovation in the Office of the Provost, Northeastern University
8:15 – 9:00 AM SGT *(8:15 – 9:00 PM EST)*	**Foundational training in Cell and Gene Therapy International Regulatory Sciences** Jared Auclair, Ph.D.

9:00 – 9:45 AM SGT *(9:00 – 9:45 PM EST)*	**Regulatory perspectives on CAR-T** Elvira Argus, FDA
9:45 – 10:30 AM SGT *(9:45 – 10:30 PM EST)*	**Overview of Best Practices** Alexandra Beumer Sassi, Ph.D., RAC. Director, CMC, Voisin Consulting Life Sciences
10:30 – 11:00 AM SGT *(10:30 – 11:00 PM EST)*	**Moderated Question and Answer Session** *Moderator:* Jared Auclair • Time for audience to ask speaker questions • Day 1 closing remarks
11:00 AM SGT *(11:00 PM EST)*	**Adjourn**

DAY 2: Thursday, May 11, 2023 (Asia); *(Wednesday, May 10, 2023 (Americas))*	
TIME (SGT/EST)	**PRESENTATION**
8:00 – 8:35 AM SGT *(8:00 – 8:35 PM EST)*	**Recap of Day 1 and Introduction to USP standards** Ben Clarke, Ph.D., Senior Scientist II, Global Biologics, USP
8:35 – 8:40 AM SGT *(8:35 – 8:40 PM EST)*	**Welcome from Moderator** Srinivasan Kellathur, Ph.D., Regional Regulatory Policy Lead, Roche
8:40 – 9:20 AM SGT *(8:40 – 9:20 PM EST)*	**Industry Case Studies** Shuyuan Zhang, Ph.D., CTO Forecyte Bio Limited
9:20 – 10:00 AM SGT *(9:20 – 10:00 PM EST)*	**Industry Case Studies** Mehrshid Alai-Safar, Ph.D., VP of Global Regulatory CMC for Kite Pharma
10:00 – 10:40 AM SGT *(10:00 – 10:40 PM EST)*	**Industry Case Studies** Lucas Chan, Ph.D., Scientific Founder and CSO for CellVec
10:40 – 10:55 AM SGT *(10:40 – 10:55 PM EST)*	**Moderated Question & Answer Session** *Moderator:* Srinivasan Kellathur, Ph.D., Regional Regulatory Policy Lead, Roche • Time for audience to ask questions
10:55 – 11:00 AM SGT *(10:55 – 11:00 PM EST)*	**Closing remarks: Summary of learning, future training opportunities, and next steps** Ben Clarke, Ph.D., Senior Scientist II, Global Biologics, USP
11:00 AM SGT *(11:00 PM EST)*	**Adjourn**