American Society for Quality (www.asq.org) – Washington DC and Maryland Metro, Section 509 (www.asq509.org)

Biomed/Biotech Special Interest Group (SIG) Meeting (http://www.asq509.org/ht/d/sp/i/31557/pid/31557)

"Regulatory Approval of Modern Gene-Based Cancer Immunotherapies – CAR T Cells – A Product Perspective"

To be presented by

Xiaobin Victor Lu, PhD

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Product Reviewer

Gene Therapy Branch, Division of Cellular and Gene Therapies

Office of Tissue and Advanced Therapies (OTAT)

Center for Biologics Evaluation and Review (CBER), US FDA

Thursday, February 1, 2018

[New venue**: CCACC, 9318 Gaither Rd. Suite 215, Gaithersburg, MD]**

6:00 – 6:20 PM – Networking; Pizza/drink

6:20 – 8:45 PM – Program

8:45 – 8:55 PM – Door-prizes drawing; Networking

Online Registration site: http://www.asq509.org/ht/d/DoSurvey/i/35817

Open to Public –

$5: non-ASQ members to cover pizza/drink cost;

Free: ASQ members, current job-seekers, CCACC volunteers/employees/members, veterans, senior citizens, past speakers, US PHS Commissioned Corp officers, teachers, students, interns, residents, postdocs, FDA Commissioner's Fellows, MJ-DC members, NTUAADC members, CAPA members, NTMUADC members, CKUAADC members, NTHUAADC members, NJTUAADC members, FAPAC members, CBA members, AAGEN members, NCARSQA members, OCA-DC members, AAMB members, ACAP members, DC Leaders Club members, BioTrain volunteers, and Tai-Chi classes students in Metropolitan DC.

Location (New Venue**): CCACC 9318 Suite 215, Gaither Rd., Gaithersburg, MD20877**

Registration Deadline: Please register by ***Thursday noon, February 1,*** *2018.*

Question: Please contact Dr. C.J. George Chang, Chair of Biomed/Biotech SIG, ASQ509; gchang2008@yahoo.com or 240-793-8425 (cell).

Driving directions: By Cars: From **I-270** (N or S bound): Take Exit 8 onto Shady Grove Dr. Drive toward east and turn left onto Gaither Rd. The building is on your left after passing a stop sign.
By Metro rail: Exit at the Red Line Shady Grove Station.

Summary

Chimeric Antigen Receptor T cell (CAR T cell) therapy is a genetically modified cellular immunotherapy and holds considerable promise for cancer therapy, as evidenced by the recent Food and Drug Administration (FDA) approval of two CAR T cell products targeting CD19 for treatment of B cell malignancies. Great interest and efforts are being generated in developing CAR T cell products and moving them from research proof-of-concepts through clinical trials, and toward commercialization. However, many challenges in the development process and the potential to cause life-threatening toxicities remain to be fully addressed.

In this presentation, Dr. Lu will introduce the CAR T cell immunotherapy concept and provide an overview of CAR T cell product manufacturing process. Dr. Lu will also discuss how the FDA manages the review process for a biologics licensure application (BLA) approval for a CAR T cell product based on the current US FDA regulations. The focus of the presentation will be on Chemistry, Manufacturing and Controls (CMC) for a CAR T cell product.

Speaker's Bio: Xiaobin Victor Lu, PhD

Dr. Xiaobin Victor Lu received his Bachelor's degree in Biochemistry from Fudan University in Shanghai, China and his PhD in molecular virology from State University of New York at Buffalo. His PhD thesis work was focused on HIV molecular biology related to mechanisms of HIV-1 Rev and Tat regulation of post transcriptional RNA processing. He was a **post-doctoral fellow** at UCSF where he studied HIV transcriptional regulation and HIV-1 Nef protein and Nef-associated proteins.

Dr. Lu worked at ONYX Pharmaceutical as a **research scientist** and continued work on HIV-Nef-associated kinases. At VIRxSYS Corporation, he served as a **senior scientist** and later a **senior director** for development of HIV- and SIV-based lentiviral vectors for clinical studies. He played an important role in the development of the first HIV-1-based lentiviral vector for human clinical studies for HIV infected individuals. Later, he served as a **senior scientific liaison** at the United State Pharmacopeia in charge of the Vaccines and Virology expert committee. Currently Dr. Lu is a **product reviewer** in the Office of Tissues and Advanced Therapies, in the Center for Biologics Evaluation and Research (CBER) of the US FDA.

This event is cosponsored by Chinese Culture and Community Service Center, Inc. (CCACC, www.ccacc-dc.org), NTU Alumni Association DC Chapter (www.ntuaadc.org), and Chinese American Professional Association DC Chapter (www.capadc.org).

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