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)

"Overview of the Regulatory Framework and FDA's Guidance for the Development and Approval of Biosimilar and Interchangeable Products in the US"

To be presented by

Sue Lim, MD, MS

(sue.lim@fda.hhs.gov)

Director

Scientific Review Staff

with Therapeutic Biologics and Biosimilars Staff

Office of New Drugs (OND)

Center for Drug Evaluation and Research (CDER), US FDA

Thursday, October 11, 2018

Venue: 9366 Gaither Rd. "1st Floor Music Room", Gaithersburg, MD 20877 (CCACC)

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

6:20 – 8:50 PM – Program

8:50 – 9:00 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 all Tai-Chi classes students in the Metropolitan Washington DC.

Registration Deadline: Please register by ***Thursday noon, October 11,*** *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

The Biologics Price Competition and Innovation Act of 2009 created an abbreviated licensure pathway for biosimilar and interchangeable products to be approved in the US. This presentation describes the regulatory framework and key scientific concepts which support the approval of these products.

Speaker

Dr. Sue Lim is the **Director** of the Scientific Review Staff with the Therapeutic Biologics and Biosimilars Staff at FDA. In this role, she provides scientific oversight and advice on the development and approval of therapeutic biologics and biosimilar products and is also involved in policy development and implementation as it pertains to biosimilar products.

Dr. Lim was previously a **Medical Officer** with the FDA's Division of Anti-Infective Products. Prior to the FDA, Dr. Lim served as an Infectious Diseases **physician** and **Associate Hospital Epidemiologist** at the University Health Network in Toronto, Canada. She received her M.D. from the University of Toronto where she also completed her residency in Internal Medicine and subspecialty training in Infectious Diseases and served as a **Lecturer** in the Faculty of Medicine. She has a Master of Science degree in Health Policy, Management and Evaluation from the University of Toronto.

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 Professionals Association of Metropolitan Washington, DC (www.capadc.org).