



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>)

“Development of New Biotechnology and Scientific Capability for Rapid/Sensitive Detection of Microbial Agents in Human Tissues Intended as Grafts or in Human Cells, Tissue, and Cellular and Tissue-Based Products (HCT/Ps)”

To be presented by

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Medical Officer and Senior Investigator
Office of Cellular Tissue Gene Therapies (OCTGT)
Center for Biologics Evaluation and Research (CBER), US FDA

Wednesday, March 23, 2016

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

6:20 – 8:45 PM – Program

8:45 – 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, 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, CKUAADC members, CCACC volunteers/employees, FAPAC members, CBA members, AAGEN members, NCARSQA members, OCA-DC members, and current job-seekers

Location: **Kelly’s Deli Conference Center, 7529 Standish Place, Rockville (Derwood, for GPS users), MD 20855**

Registration Deadline: Please register by **Wednesday noon, March 23, 2016.**

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 9A and exit from the FIRST right exit; turn left (east) onto Shady Grove Dr.; turn right (south) onto Rockville Pike (**Route 355**); turn left (east) onto East Gude Dr.; turn left (north) immediately onto Crabb’s Branch Dr.; turn left (west) immediately onto Standish Place. The first building on your right side is 7519 Standish Place; open parking). **The venue is on the first floor of 7529 Building with its external entrance opposite to the left side of 7519 building main entrance.** **By Metro trains:** Off from Red Line **Shady Grove Station**, and take RideOn **Route 59 TOWARD ROCKVILLE** and get off from “**Calhoun Place**” stop. Standish Place is next to the Bus stop. Our venue is within 2 min of walking distance from the stop.

Summary The Current Good Tissue Practices (CGTP) rule requires methods be put in place to reduce risks during tissue processing. On rare occasions, allograft tissues have transmitted infections to recipients. In most of those instances, the donor had the undetected infection at the time of death. In some other cases, tissues were contaminated during recovery, transport, processing, or storage. Many of these instances have been investigated carefully and have resulted in improved methods for screening and testing donors for infections, preventing contaminations, and removing or inactivating infectious microbes that may be present in allografts.

The FDA/CBER/OCTGT regulates human cells, tissues, and cellular and tissue-based products (HCT/Ps) in order to prevent the introduction, transmission, or spread of communicable diseases. To develop a more robust regulatory scientific infrastructure and better outreach to improve regulatory practices, as well as review performance, OCTGT has established a new Human Tissue Microbiology Laboratory (HTML) under the Division of Cellular and Gene Therapies (DCGT) in coordination with the Division of Human Tissues (DHT) since 2009. HTML supports tissue safety regulatory needs to evaluate and validate the effectiveness of various microbiology methods used by industry establishments in processing of tissues recovered from deceased donors.

This presentation introduces the development of new molecular biotechnologies for sensitive and rapid detection of a particular high-risk group of microbes in HTML to assure these highly pathogenic microbes are not present in the tissue grafts. How the laboratory is developing new capability to detect difficult-to-grow microbes in HCT/Ps and increase preparedness to address threats from newly emerging infectious pathogens will also be described. Audience will learn related molecular detection and characterization, including NGS technologies.

Speakers' Bios: Shyh-Ching Lo, PhD, MD is a **Medical Officer** in Office of Cellular, Tissue and Gene Therapies (OCTGT), CBER of FDA. He is also a **Senior Investigator** and serves as the **lead scientist** for the Human Tissue Microbiology Laboratory in OCTGT. Dr. Lo received his PhD degree (1978) from the McArdle Laboratory for Cancer Research, University of Wisconsin-Madison and MD degree (1983) from the University of Wisconsin, School of Medicine. He completed a clinical Fellowship at the National Cancer Institute, NIH. Dr. Lo is a board-certified **pathologist** and served as a **staff pathologist** at the Armed Forces Institute of Pathology (AFIP), Walter Reed Army Medical Center, Washington, DC, for 23 years before transferring to FDA in 2009. He was **chief** of Division Geographic Pathology and Division Molecular Pathobiology, respectively, at AFIP. Dr. Lo also dedicates to Tai-Chi/push-hand teaching in local communities.

Dr. Lo's laboratory at AFIP developed unique capabilities in the detection and characterization of many unusual infectious microbes, and provided diagnostic consultation services on difficult cases submitted worldwide to AFIP. Dr. Lo's earlier research efforts led to the discovery and isolation of previously unknown mycoplasmas from patients with AIDS and established that the mycoplasma-mediated cell transformation process had multiple stages in progression closely mimicking the nature of human cancers. In FDA, Dr. Lo applies his knowledge of studying tissue pathology and experience of examining infectious agents to improve safety of human tissues intended as grafts as well as human cells, tissues, and cellular and tissue-based products (HCT/Ps).