



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>)

“Potential Application of Machine Learning In Drug Development and Regulation”

To be presented by

Qi Liu, PhD, MStat

(qi.liu@fda.hhs.gov)

Team Leader, Office of Clinical Pharmacology
Center for Drug Evaluation and Research (CDER), FDA

Thursday, August 29, 2019

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, all Tai-Chi classes students in Metropolitan DC, and L4FA Community Members.

Registration Deadline: Please register by **Thursday noon, August 29, 2019.**

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

Machine learning can be used to support drug development and regulation. It can be used to aggregate data, synthesize information, seek patterns and optimize decisions. When used in drug development, it can help us understand the disease and targets, generate and evaluate drug candidates and combinations, improve trial design and advance precision medicine.

This talk will describe key areas where machine learning is making an impact in the drug development and regulatory space. Our speaker will share some examples of machine learning submissions to the FDA and some examples of machine learning use at the FDA, and then talk about some challenges and future directions of machine learning use in drug development and regulation.

Speakers



Dr. Qi Liu is a **team leader** in the Office of Clinical Pharmacology (OCP), CDER, FDA. During her 12-year career at the FDA, Qi contributed to over 200 NDA/sNDA reviews, 20 BLA/sBLA reviews, and numerous IND reviews to support oncology drug development. She co-authored about 30 manuscripts and presented on many topics (pediatric oncology, pediatric formulation, QT evaluation, dose selection, precision medicine, machine learning) at FDA Advisory Committee meetings and national conferences. She worked on several working groups for FDA guidance documents and Manual of Policies & Procedures (MAPP) development. She is the **vice chair** of the OCP Biologics Oversight Board. Qi is interested in the application of clinical pharmacology principles, innovative tools (e.g., modeling/simulation, machine learning), big data, and real world evidence to facilitate drug development and advance precision medicine.

Before joining FDA, Qi was a **senior pharmacokineticist** at Merck & Co. Inc. She obtained her Ph.D. degree in Pharmaceutics and a concurrent Master degree in Statistics from the University of Florida. In addition, Qi has a Master degree in Pharmaceutics (focus on bioanalysis) and a Bachelor degree in Clinical Pharmacy from West China University of Medical Sciences.

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).

