



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>)

“FDA/CDER Regulatory Affairs and Project Management”

To be presented by

Tamy Kim, Pharm D

(tamy.kim@fda.hhs.gov)

Associate Director for Regulatory Affairs

Office of Hematology and Oncology Products (OHOP)

Office of New Drugs (OND)

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

Thursday, May 7, 2015

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, 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, Commissioned Corp officers, 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 Thursday noon, May 7, 2015.

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

This presentation will be on Regulatory Affairs and Regulatory Project Management at the Center for Drug Evaluation and Research (CDER) of the FDA. During this presentation, the structure of the Office of New Drugs will also be presented as well as the responsibilities of the Associate Director of Regulatory Affairs, Chief Project Management Staff, and Regulatory Project Management in the Drug review divisions at the FDA.

Speaker's Bio: Tamy Kim, Pharm D

Dr. Tamy Kim is the **Associate Director for Regulatory Affairs (ADRA)** in the Office of Hematology and Oncology Products (OHOP), Center for Drug Evaluation and Research (CDER) at the US Food and Drug Administration (FDA).

As the ADRA, her responsibilities include developing and implementing policies related to the drug development and review process. Dr. Kim is most involved in developing and implementing regulatory policies and process that affect OHOP, in particular policies for Accelerated Approval, Breakthrough Therapies, Special Protocol Assessments, Expedited Reviews, and Prescription Drug User Fee Act (PDUFA). Development and implementation of these policies require application of complex regulatory expertise, communication, and collaboration with other offices within the FDA.

Dr. Kim attended Pennsylvania State University and then received her **Doctor of Pharmacy** degree from the University of the Sciences in Philadelphia in 2004. After obtaining her degree, Dr. Kim completed a **Drug Information Specialty Residency** at Purdue University in 2005. After her residency, Dr. Kim worked as a **Medical Information Manager** at a large pharmaceutical company. Dr. Kim joined FDA in 2006 as a **Regulatory Project Manager** in the Division of Neurology Products, and in 2009 she transitioned to OHOP as the ADRA.

This Biomed/Biotech SIG event is cosponsored by the Monte Jade Science and Technology Association of Greater Washington (www.MonteJadeDC.org) and NTU Alumni Association at DC (www.ntuaadc.org).