



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>)

“Career Opportunities at FDA – From A Regulatory Scientist Perspective”

To be presented by

Ke Zhang, PhD

(ke.zhang@fda.hhs.gov)

Senior Pharmacologist

Division of Gastrointestinal and Inborn Errors Products

Office of New Drugs (OND)

Center for Drug Evaluation and Research (CDER)

US Food and Drug Administration (FDA)

Thursday, May 23, 2013

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

6:20 – 8:00 PM – Program

8:00 – 8:30 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, MJ-DC members, CAPA-DC members, CCACC employees and volunteers, veterans, senior citizens, students, interns, residents, postdocs, FDA Commissioner’s Fellows, and current job-seekers

Location: Kelly’s Deli Conference Center, 7519 Standish Place, Rockville (Derwood, for GPS user), MD 20855

Registration Deadline: Please register by ***Thursday noon, May 23, 2013.***

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 with its entrance opposite to the left side of 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 speaker will discuss his daily routines as a regulatory scientist at FDA, the basic requirements to become one, and other scientific disciplines at FDA. He will also share with the audience his unique experience, lessons learned in the past, and challenges as a regulatory scientist for the past two decades while working at FDA – a dynamic organization.

Presenters' Bio: Ke Zhang, PhD

Dr. Ke Zhang was trained as a cardiovascular pharmacologist, received his Ph.D. from the Ohio State University in Columbus, Ohio, and did his postdoctoral training at Northwestern University in Chicago, IL. He joined FDA in 1994, when PDUFA I (the first authorization of Prescription Drug User Fee Act) was in its early implementation, as a pharmacologist reviewer in the Division of Gastrointestinal and Inborn Errors Products in the Office of New Drugs, Center of Drug Evaluation and Research (CDER). He is currently a senior pharmacologist reviewer.

SIG Chair's Note: On July 9, 2012, the fifth authorization of PDUFA was signed into law through the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012. Each PDUFA authorization period has been 5 years.

<http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm>

This Biomed/Biotech SIG event is cosponsored by the Monte Jade Science and Technology Association of Greater Washington (www.MonteJadeDC.org) and the Chinese American Professionals Association (www.capadc.org).