



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>)

“Generic Drugs – Application and Regulatory Review”

To be presented by

Naiqi Ya, PhD (naiqi.ya@fda.hhs.gov)
Deputy Director, Division of Chemistry IV
Office of Generic Drugs, Office of Pharmaceutical Science
Center of Drug Evaluation and Research (CDER)
US Food and Drug Administration (FDA)

Thursday, September 26, 2013

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, MJ-DC members, CAPA-DC members, FAPAC members, CCACC volunteers/employees, 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, September 26, 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 following topics will be briefly discussed:

1. Compare and contrast between the generic drugs and new drugs,
2. Generic Drug application filing and regulatory review,
3. Achievements and challenges in the regulatory review for generic-drug applications,
4. Career opportunities in generic-drug regulatory review.

Presenter's Bio: Naiqi Ya, PhD

Dr. Naiqi Ya is the **Deputy Director** in Division of Chemistry IV, Office of Generic Drugs, Office of Pharmaceutical Science, Center of Drug Evaluation and Research, US FDA. He joined the FDA as a **Review Chemist** in 1996, and was promoted to a **Team Leader** in 2005 and to his current position in 2010.

Prior to joining the FDA, he served as a **Senior Chemist** in R&D department at Biocraft Laboratories, Inc. He received his PhD degree in bioanalytical and biophysical chemistry from New York University.

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 of Metropolitan Washington DC (www.capadc.org).