**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).**