



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>)

“How to Avoid Common CMC Deficiencies in INDs and NDAs”

To be presented by

Ramesh Raghavachari, PhD

(ramesh.raghavachari@fda.hhs.gov)

Chief, Post-marketing Branch

Division III, Office of New Drug Quality Assessment (ONDQA)

Center for Drugs Review and Research (CDER)

US Food and Drug Administration

Thursday, February 27, 2014

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, teachers, students, interns, residents, postdocs, FDA Commissioner’s Fellows, MJ-DC members, NTUAADC members, CAPA members, FAPAC members, CCACC volunteers/employees, and current job-seekers

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

Registration Deadline: Please register by **Thursday noon, February 27, 2014.**

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:

This discussion will be a general outline of what CMC information is expected by the FDA in terms of submissions to the investigational new drug applications (INDs) and new drug applications (NDAs). The discussion will be a quality perspective with examples.

(Note: CMC: Chemistry, Manufacturing, and Controls)

Presenter's Bio: Ramesh Raghavachari, PhD

Dr. Ramesh Raghavachari obtained his MS and PhD in organic chemistry from Temple University, Philadelphia, PA under the guidance of Professor Daniel Swern and Professor Grant Krow in the areas of synthetic methodology-based physical organic chemistry and methodology-based synthesis of anti-cancer agents. His post-doctoral work was in nucleic acid chemistries aiming at anti-HIV compounds. He furthered his nucleic acid experience in the area of genomic technologies using fluorescent near-infrared dyes and its applications supporting the Human Genome Project both in academia and later in the biotechnology industry.

Dr. Raghavachari joined FDA in 2003 as a **Chemistry Reviewer**, he was promoted as a **Team Leader** in 2005, and currently **Chief** of Post-Marketing Branch for Division III in the Office of New Drug Quality Assessment in CDER.

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).