



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 Drug Manufacturing Facility Inspections & Current Good Manufacturing Practices (cGMP)”

To be presented by

CDR Denise DiGiulio, RPh
(denise.digiulio@fda.hhs.gov)

and

LCDR Tara Goen Bizjak, MS, CQE
(tara.goen@fda.hhs.gov)

Office of Pharmaceutical Quality
Center for Drug Evaluation and Research (CDER), US FDA

Thursday, June 4, 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, June 4, 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 that stop.

Summary

This presentation will introduce current good manufacturing practices (cGMP) for drugs and what to expect from an FDA inspection of a drug manufacturing facility. You will learn about the different kinds of inspections that the FDA performs for CDER regulated products, the standards by which the drug manufacturing facility will be assessed (e.g., cGMP regulations), and what happens when deviations are observed.

Speakers' Bios:

CDR Denise DiGiulio, RPh

Commander Denise DiGiulio, is a **NDA/ANDA Facility Reviewer** in the Office of Process and Facilities in CDER. She has been with FDA for 16 years. She began her service with FDA at the Philadelphia and New Jersey District Offices as an **investigator** and performed primarily drug manufacturing inspections, both domestic and international. In 2009, she transferred to CDER Office of Compliance as a **compliance officer** in the Division of Good Manufacturing Practice Assessment (DGMPA). In 2015, she transferred to her current position. DiGiulio's main responsibility in the Office of Process and Facilities includes the scientific review and quality evaluation of the manufacturing process and facilities filed in A/NDAs. As a member of the review team she collaborates with other members of CDER and ORA in order to integrate manufacturing process review and inspection assessment to provide for an enhanced quality assessment of the application being reviewed. She continues to be a **lead investigator** for drug manufacturing CGMP pre-approval and surveillance inspections. She is an **officer** in the United States Public Health Service (US PHS). DiGiulio received her BS in pharmacy from Rutgers College of Pharmacy and is a **registered Pharmacist** in New Jersey.

LCDR Tara Goen Bizjak, MS, CQE

Lieutenant Commander Tara Goen Bizjak is an **engineering officer** in the US PHS and a **Senior Science Policy Advisor** at the FDA. She works in the Office of Policy for Pharmaceutical Quality in the area of developing new regulations, guidance, and standards. LCDR Bizjak has been with the FDA for almost 13 years, starting as a **field investigator** in the New Jersey District, primarily focusing on drug manufacturing and current good manufacturing practice (cGMP) inspections. In 2007, she transferred to CDER to the area of a manufacturing and product quality and was a **subject matter contact** for several cGMP topics, including pre-approval inspections, continuous manufacturing, pharmaceutical quality systems, water quality, and scale-up issues. Prior to her current role, she served in multiple roles, including **branch chief** and **senior advisor**. LCDR Bizjak received her BS in Chemical Engineering from Cornell University, a MS in Biomedical Sciences from the University of Medicine and Dentistry of New Jersey, and is an ASQ (American Society for Quality) **Certified Quality Engineer**.

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).