



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>)

“Enabling Programs and Leadership to Support FDA/CDER’s Mission – A Perspective from the Office of Translational Sciences”

To be presented by

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Director, Office of Translational Sciences
Center for Drug Evaluation and Research (CDER)
US Food and Drug Administration

Thursday, April 10, 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, CCACC volunteers/employees, FAPAC members, CBA members, Commissioned Corp officers, 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, April 10, 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:

A rapid and ever-increasing trend exists in the globalization of drug research and development applying both scientific innovation and modern technologies. The regulatory authorities for medicinal products around the world need to have enabling programs, effective initiatives, mission-focus operations, and visionary leadership to embrace those changes and related challenges.

Our discussion will focus on the programs, initiatives, and leadership within the Office of Translational Sciences of FDA/CDER to support and fulfill the critical mission protecting and promoting the public health through the regulation, enforcement, and education.

Presenter’s Bio: ShaAvhrée Buckman-Garner, MD, PhD, FAAP

ShaAvhrée Buckman-Garner, MD, PhD, FAAP, is the **Director** for the Office of Translational Sciences (OTS). OTS is a super office providing oversight for the Office of Biostatistics, Office of Clinical Pharmacology, Office of Computational Science, and critical path initiatives serving as an interdisciplinary bridge linking internally with other CDER offices and externally to the scientific community as an opportunity to create meaningful regulatory and therapeutic changes. Dr. Buckman has served as the leader for this office since September 2007.

Dr. Buckman joined the FDA in 2002 as a **medical officer** in the Division of Pediatric Drug Development, Office of Counter Terrorism and Pediatric Drug Development, where she went on to serve as a **medical team leader** prior to joining OTS. During her tenure at FDA, Dr. Buckman has served on numerous **boards** aimed at public private partnerships to support scientific innovation including the Biomarker Consortium Executive Committee, the Serious Adverse Events Consortium, as well as various efforts involving the Critical Path Institute. Dr. Buckman is a **board certified Pediatrician** who received her MD and PhD in molecular cell biology from Washington University School of Medicine. She completed her pediatric specialty training at Baylor College of Medicine, Texas Children’s Hospital.

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).