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)

"Winning Clinical Trials – Some Statistic Review Perspectives"

To be presented by

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and

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Office of Biostatistics, Office of Translational Sciences

Center for Drug Evaluation and Research (CDER), US FDA

Thursday, May 21, 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, May 21,*** *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 the stop.

Summary This talk will describe the role of statistics in making approval decisions regarding INDs, NDAs and BLAs at the Center for Drug Evaluation and Research. In addition, we will discuss current review practice and provide an update on the development of laws and "binding guidance" to support new requirements for the submission of CDISC standardized study data and eCTDs.

Speakers' Bios:

Steve E. Wilson, DrPH, CAPT USPHS Dr. Wilson has worked as a **Statistical Reviewer** and **Supervisory Mathematical Statistician** in FDA's CDER for 28 years (this week) and is currently the **Director** of the Division of Biometrics III in the Office of Biostatistics, Office of Translational Sciences. He received his doctorate in Biostatistics from the University of North Carolina, Chapel Hill, in 1984.

Steve's professional experience includes statistical research / management positions with the East West Center in Hawaii, the Indonesian Central Bureau of Statistics (Biro Pusat Statistik), the University of North Carolina, the Federated States of Micronesia, and the World Bank. His professional interests and activities are currently focused on issues related to the development of standards, improvements in clinical trials science and practice, review of new pharmaceutical products, and the application of new technology and processes in the regulatory environment.

Benjamin P. Vali, MS Ben graduated from the University of Wisconsin-Madison with a Master of Science (MS) in statistics. Following his studies, Ben conducted research in clinical trial methodology as a **fellow** at the National Cancer Institute (NCI) in Bethesda, MD, and then moved on to Novartis Pharmaceuticals in Basel, Switzerland where he continued his clinical trials research. Afterwards, moving to a CRO -- Pharmaceutical Product Development (PPD), Inc. in Austin, TX -- he worked as **professional biostatistician** for two years. After PPD, Ben joined the US FDA in October 2008, and is currently **a statistical reviewer** in the Office of Biostatistics, Office of Translational Sciences at the CDER. Ben's regulatory review work is in conjunction with the Division of Gastroenterology and Inborn Errors Products (DGIEP), where he is focusing on Inborn Errors of Metabolism and rare diseases. In addition to his regulatory review work, his "extracurricular professional activities" are geared toward health care informatics.

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).