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)

"Regulations and Specific Clinical Trial Designs"

To be presented by

Robert Temple, MD

(robert.temple@fda.hhs.gov)
Deputy Center Director for Clinical Science &
Acting Deputy Director, Office of Drug Evaluation I (ODE-I)
Center for Drug Evaluation and Research (CDER), US FDA

Thursday, February 12, 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 – Please park at 7519 Standish Place parking lot for close access to venue.

Registration Deadline: Please register by ***Thursday noon, February 12****, 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

Our speaker will discuss the development of standards for clinical trials beginning with the 1962 Food Drug and Cosmetic Act and continuing with subsequent regulations and extensive guidance as well as experience.

Particular study designs and their difficulties will be considered, including placebo, dose-response, active (especially non-inferiority trials) and historical controls, as well as what we have learned about the need for blinding, accounting for all patients, planning analyses before the trial data are seen, and other matters. Specific trial designs that can improve the likelihood of trial success will also be discussed, notably enrichment designs and randomized withdrawal designs, as well as adaptive designs, large simple trials, and the potential for master protocols.

Speaker's Bio: Robert Temple, MD

Dr. Robert Temple has been **Deputy Center Director** for Clinical Science at FDA's Center for Drug Evaluation and Research since 2009, participating in the direction of the Center's operations. He is also **Acting Deputy Director** of the Office of Drug Evaluation I (ODE-I). ODE-I is responsible for the regulation of cardio-renal, neuropharmacologic, and psychopharmacologic drug products.

Dr. Temple served as **Director**, Office of Medical Policy from 1999-2009. The Office of Medical Policy is responsible for regulation of drug promotion through the Office of Prescription Drug Products (OPDP; formerly, Division of Drug Marketing, Advertising, and Communication (DDMAC)) and for assessing quality of clinical trials. Dr. Temple has a long-standing interest in the design and conduct of clinical trials and has written extensively on this subject, especially on choice of control group in clinical trials, evaluation of active control and non-inferiority trials, trials to evaluate dose-response, and trials using "enrichment" designs.

Dr. Temple received **2014 Harvey W. Wiley Lectureship award** from the FDA Alumni Association (FDAAA) at the Food and Drug Law Institute (FDLI) Annual Conference. This prestigious award is named in honor of Harvey W. Wiley, MD, the renowned physician-chemist who spearheaded the passage of the Federal Food and Drug Act of 1906; Dr. Wiley was the first FDA Commissioner. In a memo to FDA's CDER staff, CDER Director Dr. Janet Woodcock noted that with receipt of this award that Dr. Temple is being recognized "For lifetime commitment to FDA's public health mission because of his incredibly influential career at FDA, and the tremendous impact he has had on advancing thinking on clinical trials and the drug development process as a whole." (http://www.fdaaa.org/activities/2014/050414.php)

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).