American Society for Quality (www.asq.org) – Washington D.C. and Maryland Metro, Section 509 (www.asq509.org)

Biomed/Biotech Special Interest Group (SIG) Meeting

GLP Modernization – An Update

To be presented by

C.T. Viswanathan, MS', PhD

Associate Director
Division of Scientific Investigations (DSI)
Office of Compliance (OC)
Center for Drug Evaluation and Research (CDER), US FDA

Thursday, August 25, 2011

6:00 – 6:20 PM – Networking; Pizza/drink
6:20 – 8:30 PM – Program (a 10-min intermission at mid point)
8:30 – 8:50 PM – Door-prizes drawing; Networking

Online Registration site: http://www.asq509.org/ht/d/DoSurvey/i/35817

Open to Public - **$5 for non-ASQ members to cover pizza/drink cost; Free to ASQ Members, students, local interns, postdocs, and FDA Commissioner's Fellows**

Location: Kelly's Deli Conference Center, 7519 Standish Place, Rockville, MD 20855
Registration Deadline: Please register by ***Thursday noon, August 25****, 2011.*
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 Car: 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 train**: 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: "GLP Modernization – An Update"

- **Issues leading to the need for modernization;**
- **What are the issues;**
- **Unresolved issues; and**
- **Desirable future state**

Nonclinical (preclinical) data generated in the early stages of drug development are significant and form the basis of understanding for possible **safety concerns** of the **drug candidates**. This information is often critical in allowing the **clinical trials in humans** to proceed. Current **Good Laboratory Practice** (**GLP**) **regulations** provide a framework to conduct nonclinical studies in a satisfactory manner. Optimization of these regulations will provide further opportunities to effectively collect robust and quality data.

This presentation will discuss the need for modernization, the issues that need to be resolved, the outdated practices that need to be eliminated, and ways for possibly reducing the regulatory burden. The ways in which your future work can be affected and the ongoing review of the **comments for ANPRM** (**advanced notice for proposed rule making**) will be discussed. The desirable future direction can be enabled by collaborative efforts from both Industry and the Regulatory Agency.

Presenters' Bios:

C.T. Viswanathan, MS', PhD

Dr. Viswanathan is currently the **Associate Director** in the Division of Scientific Investigations, Office of Compliance, Center for Drug Evaluation & Research, US FDA. He has policy oversight of the scientific and regulatory administration of GLP and Bioequivalence Inspectional programs, and is active in Harmonization and Globalization aspects of those areas of Regulatory Compliance.

Dr. Viswanathan received his first MS in Chemistry from Marquette University, Milwaukee, and his second MS in Pharmacology and PhD in Pharmacokinectics from the University of Wisconsin, Madison, WI. Following post-doctoral research at the University of Georgia and the University of Washington, Seattle, WA, he joined US FDA. In FDA/CDER, he has served as **clinical pharmacology reviewer**, followed by as the **Chief** of Pharmacokinetics Branch, and the **Acting Director** of the Division of Biopharmaceutics (currently Division of Clinical Pharmacology), prior to joining the Office of Compliance.

He has represented FDA in numerous national and international meetings. He has served on many **committees** in FDA, NIH, PhRMA, SQA, BSAT, and AAPS. He is a past **Chair** of the Regulatory Sciences section and a **Fellow** of the AAPS; he is also the recipient of numerous FDA awards. Dr.Viswanathan is the **Chair** of the FDA GLP Modernization Working Group, and represents all Centers of FDA in OECD for GLP.

Dr. Viswanathan has taught Pharmacology, Drug Metabolism, Pharmacokinetics, and Biopharmaceutics at the University of Wisconsin, University of Montreal, FDA Staff College, and NIH Graduate School; and has authored several research publications. He currently also serves as an **Adjunct Professor** in the School of Pharmacy in the University of Wisconsin, Madison, WI.