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

Overview of Biologics Drug Inspections

To be presented by

Gang Wang, Ph.D.

Expert Biologist

Division of Manufacturing and Product Quality

Office of Compliance and Biologics Quality

Center for Biologics Evaluation and Research (CBER), FDA

Thursday, September 29, 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, September 29****, 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: "Overview of Biologics Drug Inspections"

This presentation will provide an overview of the biological drug products regulated by the Center for Biologics Evaluation and Research (CBER), FDA; the laws and regulations including the current good manufacturing practices (CGMP) that are applicable to the inspection of manufacturing facilities; and how FDA uses the system-based, risk management approach, with focus on the six key systems and three critical elements, to conduct pre-license and pre-approval inspections. We will also discuss some of the most common deficiencies observed during the inspections, and the regulatory actions that FDA may take to stop and prevent the violations and to ensure the safety, purity, potency, effectiveness, and quality of biological drug products.

The major topics will include the following:

- Introduction of CBER Regulated Products
- Overview of Biological Drug Inspections
- Observations Found during Drug Inspections
- Post-market Regulatory Actions

Presenters' Bios: Gang Wang, Ph.D. (gang.wang@fda.hhs.gov)

Dr. Gang Wang is currently in transition to serve as the **Assistant Country Director** for FDA's China Office, Office of International Programs, Office of Commissioner, FDA. At this position, he holds the responsibilities for policy analysis, capacity building, and collaborative programs related to drugs and biologics. He will be working at the FDA China Office in Beijing, China.

Prior to joining FDA China Office, Dr. Wang was a **Senior Reviewer**, **Lead Inspector** and an **Expert Biologist** in the Division of Manufacturing and Product Quality (DMPQ), Office of Compliance and Biologics Quality (OCBQ), Center for Biologics Evaluation and Research (CBER), FDA. His main responsibilities included reviewing and evaluating the Chemistry, Manufacturing and Control (CMC) and CGMP issues of various applications/submissions for biological products and conducting pre-license and pre-approval inspections of domestic and international pharmaceutical companies for manufacturing of biological drug products. Dr. Wang is a peer-reviewed expert on CGMP and manufacturing of biological drugs, with special expertise in cellular and gene therapy products.

Dr. Wang received his B.S. in biochemistry from Nanjing University in China and Ph.D. in pharmacology and toxicology from Dartmouth Medical School. He conducted his postdoctoral training in cancer immunotherapy at the National Cancer Institute (NCI) in NIH. He was an **Assistant Professor** and **Principal Investigator** at the University of Texas M.D. Anderson Cancer Center prior to joining FDA in 2005.