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

"Development of Molecular Diagnostics – An FDA Perspective"

To be presented by

Yun-Fu Hu, MS, PhD (yun-fu.hu@fda.hhs.gov)

Associate Director

Division of Immunology and Hematology Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

Center for Device and Radiological Health (CDRH), US FDA

Wednesday, August 15, 2012

6:00 – 6:20 PM – Networking; Pizza/drink

6:20 – 8:30 PM – Program

8:30 – 8:45 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, students, local interns, residents, postdocs, FDA Commissioner's Fellows, and current job-seekers

Location: Kelly's Deli Conference Center, 7519 Standish Place, Rockville, MD 20855
Registration Deadline: Please register by ***Wednesday noon, August 15****, 2012.*
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: "Development of Molecular Diagnostics – An FDA Perspective"

This presentation will provide the audience with an introduction to federal regulation of *in vitro* diagnostic medical devices, premarket submissions, and FDA review processes. Some examples of the issues and challenges, noted in the review process, which could help device manufacturers to design and manufacture better molecular devices and to design and conduct more appropriate validation studies, for a quicker entry to the very competitive market, will also be discussed.

Presenter's Bio: Yun-Fu Hu, MS, PhD

Dr. Yun-Fu Hu was born and raised in China. Upon completion of his studies in animal sciences and veterinary medicine at ***Central China Agricultural University***, he went to ***the Ohio State University*** (Columbus, OH) to pursue advanced degrees, training, and career opportunities. He studied reproductive endocrinology for his MS degree and cancer biology for his PhD degree.

He spent 5 years at Fox Chase Cancer Center in Philadelphia initially as a **postdoctoral fellow**, then **Research Associate**, and eventually a **Staff Fellow** for the last 2 years there. His research interests centered around molecular mechanisms of carcinogenesis. He then joined Becton Dickson in Baltimore as a **Project Scientist** leading the development of a molecular diagnostic test for melanoma for 2 years before he was recruited to work at GlaxoSmithKline (GSK) as an I**nvestigator**. He was promoted to **Group Manager** 3 years later. His group was mainly responsible for discovery of biomarkers and development of biomarker tests in support of GSK drug development programs. After more than 6 years at GSK, he joined a biotech company in RTP as the **Director** of Diagnostics Development to oversee the company's diagnostics programs including discovery of metabonomic biomarkers and development of *in vitro* diagnostics.

He joined FDA 3.5 years ago as a **Scientific Reviewer** in Hematology branch of the Division of Immunology and hematology Devices at CDRH's Office of In Vitro Diagnostic Device Evaluation and Safety and was promoted to **Associate Director** last summer in charge of the Immunology branch of that Division. His group is responsible for review and clearance or approval of a variety of immunology and molecular diagnostic devices such as cancer diagnostics and genetic tests as well as tests for autoimmune diseases (e.g., Celiac disease, Crohn's disease), allergies (e.g., pollen allergy), etc. His group has recently approved several companion diagnostics that are intended to select the right patients for the right therapies.