



American Society for Quality ([www.asq.org](http://www.asq.org)) – Washington DC and Maryland Metro, Section 509 ([www.asq509.org](http://www.asq509.org))

Biomed/Biotech Special Interest Group (SIG) Meeting  
(<http://www.asq509.org/ht/d/sp/i/31557/pid/31557>)

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## “Development of Companion Diagnostics – An FDA Perspective”

To be presented by

**Yun-Fu Hu, PhD, RAC**

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Deputy Director

Division of Molecular Genetics and Pathology  
Office of *In Vitro* Diagnostics and Radiological Health (OIR)  
Center for Device and Radiological Health (CDRH), US FDA

**Thursday, October 6, 2016**

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, US PHS Commissioned Corp officers, teachers, students, interns, residents, postdocs, FDA Commissioner’s Fellows, MJ-DC members, NTUAADC members, CAPA members, NTMUADC members, CKUAADC members, NTHUAADC members, CCACC volunteers/employees, FAPAC members, CBA members, AAGEN members, NCARSQA members, OCA-DC members, AAMB members, ACAP members, 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, October 6, 2016.**

**Question:** Please contact Dr. C.J. George Chang, Chair of Biomed/Biotech SIG, ASQ509; [gchang2008@yahoo.com](mailto: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

Remarkable advances in the understanding of molecular mechanisms influencing neoplastic development and progression have spurred interest in molecular diagnostics and targeted cancer therapeutics. Approximately one in five original novel drugs approved by the US FDA since 2010 is considered a “targeted” therapy. Diagnostic tests that are essential to the safe and efficacious use of a drug are called “companion diagnostics”. Co-development and co-approval of therapeutics and companion diagnostics have provided significant benefits to cancer patients. However, the current co-development and co-approval paradigm has also brought many scientific, economical and regulatory challenges that pharmaceutical companies, device manufacturers, clinical labs and regulatory agencies will have to work together to overcome.

With the advent and rapid adoption of next generation sequencing (NGS) technology for biomarker identification and clinical testing, it is conceivable that NGS may soon become the platform of choice to be used for genetic testing of a large array of genes for guiding patients to different targeted therapies. This presentation is intended to provide an overview of co-development of targeted therapeutics by pharmaceutical companies and device manufacturers, and discuss some regulatory challenges and opportunities for development of original and follow-on companion diagnostics, especially in the areas of liquid biopsy and NGS-based oncology panel.

## Speaker’s Bio: Yun-Fu Hu, PhD, RAC



Dr. Yun-Fu Hu is currently the **Deputy Director** of the Division of Molecular Genetics and Pathology in the Office of *In Vitro* Diagnostics and Radiological Health at FDA’s Center for Devices and Radiological Health.

Dr. Hu completed his undergraduate studies in China, and received his MS and PhD degrees from the Ohio State University. After 5 years of studies on the cellular and molecular mechanisms of breast cancer development at Fox Chase Cancer Center initially as a **postdoctoral fellow**, then **research associate** and eventually a **Staff Fellow** for the last 2 years there, he joined Becton Dickson as a **Project Scientist** leading the development of a molecular diagnostic test for melanoma. He led biomarker discovery and test development at GSK as an **Investigator** and then **Group Manager** for more than 6 years before joining Metabolon as the **Director** of Diagnostics Development to oversee the diagnostics research and development programs.

Dr. H joined FDA as a **Scientific Reviewer** in 2009 and was promoted to **Associate Director** in 2011. He became the **Chief** of the Molecular Pathology and Cytology Branch of the Division of Molecular Genetics and Pathology in 2012, and was promoted to his current position in 2015 providing oversight of regulatory reviews of genetic tests, oncology companion diagnostics, and anatomical / molecular pathology and cytology devices.

This event is cosponsored by NTU Alumni Association DC Chapter ([www.ntuaadc.org](http://www.ntuaadc.org)), Chinese American Professional Association DC Chapter ([www.capadc.org](http://www.capadc.org)), and Association of Chinese American Physician Mid-Atlantic Chapter (ACAP-MAC).