



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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## “The Role of Clinical Pharmacology in Risk-Benefit Assessment of New Drugs”

To be presented by

**Shiew-Mei Huang, PhD**  
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Deputy Director  
Office of Clinical Pharmacology  
Office of Translational Sciences  
Center for Drug Evaluation and Research (CDER)  
US Food and Drug Administration (FDA)

**Wednesday, June 5, 2013**

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

6:20 – 8:45 PM – Program

8:45 – 8:00 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](#), [MJ-DC members](#), [CAPA-DC members](#), [ASCPT members](#), [CCACC volunteers/employees](#), [veterans](#), [senior citizens](#), [students](#), [interns](#), [residents](#), [postdocs](#), [FDA Commissioner’s Fellows](#), and [current job-seekers](#)

**Location:** Kelly’s Deli Conference Center, 7519 Standish Place, Rockville (Derwood, for GPS user), MD 20855

**Registration Deadline:** Please register by **Wednesday noon, June 5, 2013.**

**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 with its entrance opposite to the left side of 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:** US Food and Drug Administration (FDA) has identified innovation in clinical evaluations as a major scientific priority area. Provisions in the recently enacted US FDA Safety and Innovation Act (FDASIA) and the reauthorized Prescription Drug User Fee Act V (PDUFA V) underscore the need for and importance of developing new approaches to streamline drug development and regulatory evaluation. This presentation provides case studies and updates to describe the efforts by the FDA's Office of Clinical Pharmacology in its development and application of regulatory science in the risk-benefit assessment of new drugs. Key issues and challenges are identified that need to be addressed to evaluate "subset" effects (based on subtype of diseases, age, sex, race, genetics, organ dysfunctions, concomitant medications, etc.).

**Presenters' Bio:** Dr. Shiew-Mei Huang is currently **Deputy Director**, Office of Clinical Pharmacology, Center for Drug Evaluation and Research (CDER), FDA. She received her B.S. in Pharmacy from National Taiwan University, School of Pharmacy and her Ph.D. from University of Illinois, Medical Center in Pharmacokinetics and Biopharmaceutics. Dr. Huang has 15+ years of drug development experience (Ortho pharmaceutical Corp. and Dupont-Merck Pharmaceutical Company) before joining the FDA in 1996. She **chairs** CDER working groups that published a draft guidance on drug interactions in 2012 and a draft guidance on pharmacokinetics in renal impairment in 2010. She is a **member** of the FDA Pharmacogenomics Working Group and CDER Hepatic impairment working group. She is an **alternate member** of the FDA Drug Safety Oversight Board.

Dr. Huang has published over 140 peer-reviewed articles and book chapters focusing on topics in clinical pharmacology, drug metabolism/interactions, and pharmacogenomics areas and has been invited to present more than 60 presentations in the past 6 years (2008-2013) at national and international meetings and workshops. She is an **associate editor** for a Nature journal "Clinical Pharmacology and Therapeutics" and on the **editorial boards** of several other journals, including Expert Review in Clinical Pharmacology, Biomarkers in Medicine, Journal of Clinical Pharmacology, Expert Opinion- Pharmacotherapy, and Pharmacogenomics. She has received many awards, including an FDA Outstanding Achievement Award, FDA Clear Communication Award, and FDA Distinguished Service Award. Dr. Huang is an AAPS **Fellow** (American Association of Pharmaceutical Scientists), a JSSX **Fellow** (Japanese Society of the Study of Xenobiotics), and a **diplomat** of the American Board of Clinical Pharmacology.

Dr. Huang is an **Adjunct Professor** at the School of Pharmacy, University of Maryland and has been a faculty member of an elective course on pharmacogenomics since 2008. She was the **President** (2009-2010) of the American Society for Clinical Pharmacology and Therapeutics (ASCPT). She also served as **Chair**, Executive Committee, Chinese American Community Center in Delaware (1996); **President**, American Chinese Pharmaceutical Association (ACPA; 2000); and **President**, Chinese American Professionals Association of Metropolitan Washington DC (CAPA; 2002). She was the **Founder** of FDA White Oak Toastmasters (TM) Club and the **Governor** for Area 55, Division E, District 36 (2005-2006) of the International Toastmasters Club.

**This Biomed/Biotech SIG event is cosponsored by the Monte Jade Science and Technology Association of Greater Washington ([www.MonteJadeDC.org](http://www.MonteJadeDC.org)) and the Chinese American Professionals Association of Metropolitan Washington DC ([www.capadc.org](http://www.capadc.org)).**