



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 Biological Drug Development”

To be presented by

**Yow-Ming Wang, PhD**

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Biologics Team Leader

Office of Clinical Pharmacology Division III

Office of Translational Sciences

Center for Drug Evaluation and Research (CDER), FDA

**Thursday, February 25, 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, CKUAADC members, CCACC volunteers/employees, FAPAC members, CBA members, AAGEN members, NCARSQA members, OCA-DC 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, February, 25, 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

This presentation provides a high level understanding of the basic principles of clinical pharmacology and its role in drug development from phase 1 through phase 3 which ultimately leads to product approval by FDA. I will introduce how the clinical pharmacology data are captured during drug development and then communicated to patients, physicians, and the healthcare community at the time of product approval.

Among the FDA regulated biological products, the focus of this presentation is on the protein therapeutic agents reviewed in Center for Drug Evaluation and Research (CDER). I will cover briefly the FDA’s definition of biological products and the FDA approved biological products. I will also use case examples to illustrate the application of clinical pharmacology principles in support of regulatory submission and product approval and additional clinical pharmacology considerations for biological products.

## Speaker’s Bio: Yow-Ming Wang, PhD

Dr. Yow-Ming Wang is the **biologics team leader** in the Division III of the Office of Clinical Pharmacology at FDA. The biologics team at DCP III is responsible for reviewing submissions of biologic products in three clinical divisions. Dr. Wang joined FDA in March 2011.

Prior to the FDA, she spent many years in the pharmaceutical industry with experience in the discovery research, preclinical development, and clinical development of small molecules and large molecules. From 2004 to 2011, she worked at Amgen where she supported multiple biologic products in clinical development, in registration phase, and in post-marketing phase. Prior to that, Dr. Wang supported small molecule drug discovery and development for 11 years at Vertex Pharmaceuticals and at Parke-Davis Pharmaceutical Research. She received her PhD degree from The Ohio State University College of Pharmacy with a research focus on Pharmacokinetics and Biopharmaceutics.