**American Society for Quality (www.asq.org) – Washington DC and Maryland Metro, Section 509 (www.asq509.org)**

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

# "Overview of FDA's Postmarket Drug Safety and Surveillance"

**To be presented by**


## Min Chen, MS, RPh

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**Acting and Deputy Director**
**Division of Pharmacovigilance**
**Office of Surveillance and Epidemiology**
**CDER, US FDA**


## Thursday, August 22, 2013

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, MJ-DC members, CAPA-DC members, FAPAC 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 ***Thursday noon, August 22****, 2013.*
**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 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:

Ms. Min Chen will share her professional experience for 23 years in the area of postmarketing drug safety in the FDA. Therapeutic drug and biologic products are approved for marketing based on a comprehensive review of safety and efficacy data submitted by applicants. There are limitations in premarketing clinical trials to study the safety for products. Ms. Chen will give an overview of how spontaneously originated adverse event reports and other available data are utilized to monitor, detect, and assess product safety signals. When available, pharmacoepidemiologic methodology is used to estimate the risk of adverse effects of a product on exposed populations. Such efforts will enable making appropriate and timely regulatory actions to assure the safe use of the medical products.

## Presenters' Bio: Min Chen, MS, RPh

Ms. Min Chen is currently the **Acting and Deputy Director** of the Division of Pharmacovigilance, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research at the US Food and Drug Administration (FDA). Ms. Chen is a **clinical pharmacist** and joined the FDA over 26 years ago.

At the FDA, Ms. Chen has involved in all key aspects of postmarketing safety activities, most notably directing the pharmacovigilance practice using available data sources for safety signal detection, evaluation and recommendation for management of risk for all US marketed medicinal products, and the development of the FDA Adverse Event Reporting System (FAERS) database. She is also closely involved with the postmarketing reporting regulation and guidance development both in the FDA and the International Conference on Harmonisation (ICH). Ms. Chen has **chaired** international pharmacovigilance conferences with regulatory authorities from the European Medicines Agency (EMA), Canada, Australia, New Zealand, and Singapore. She has received over 25 awards during her time at the FDA, including the highest citation award from the FDA Commissioner.

Ms. Chen is a graduate of the National Taiwan University (NTU) College of Pharmacy, and holds a Master of Science in Pharmacology from the NTU and a Pharmacy degree from the University of Missouri, Kansas City. She is a **Senior Adviser** to the Chinese American Professionals Association of Metropolitan Washington DC.

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