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)

"Clinical Endpoint Bioequivalence (BE) Study Review in ANDA Submissions"

To be presented by

Ying Fan, MS, PhD
(ying.fan@fda.hhs.gov)
Team Lead, Division of Clinical Review
Office of Generic Drugs
Center for Drug Evaluation and Review (CDER), US FDA

Thursday, January 11, 2018

[New venue**: US Center for Chinese Medicine (USCCM) by BUCM]**

6:00 – 6:20 PM – Networking; Pizza/drink
6:20 – 8:45 PM – Program
8:45 – 8:55 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, NJTUAADC members, CCACC volunteers/employees, FAPAC members, CBA members, AAGEN members, NCARSQA members, OCA-DC members, AAMB members, ACAP members, DC Leaders Club members, BioTrain volunteers, current job-seekers, Tai-Chi classes students, and USCCM-BUCM frinends.

Location (New Venue**): USCCM by BUCM 9600 Blackwell Rd. 3rd Floor, Rockville, MD 20850**

Registration Deadline: Please register by ***Thursday noon, January 11,*** *2018.*
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 8** onto Shady Grove Dr.; drive toward west and turn right onto Blackwell Rd. The building is on your left had side. **By Metro rail: Exit at the Shady Grove Station.**

Summary

The speaker will give an overview of the clinical endpoint BE study review in abbreviated new drug application (ANDA) submissions for generic drugs. The presentation will include the definition of the clinical endpoint BE study, when to do the clinical endpoint BE study, and who are involved in the clinical endpoint BE study review, etc. It will also include an overview for the study design for the clinical endpoint BE study for the nasal spray products.

Speaker's Bio: Ying Fang, MS, PhD

Dr. Ying Fan joined FDA in 2008 and is currently a **Team Leader** in Division of Clinical Review, Office of Generic Drugs (OGD), Center for Drug Evaluation and Research (CDER). Her current main responsibilities include reviewing drug products submitted in Abbreviated New Drug Applications (ANDAs), to determine the adequacy of the data from clinical endpoint bioequivalence studies and skin irritation, sensitization and adhesion studies based on study design, methodology, and statistical analysis. In addition to the review work, she is actively involved in research projects and published more than 30 journal articles and abstract. She is a **vice president** for the American Chinese Pharmaceutical Association (ACPA) since 2009.

Before joining CDER/OGD, she was a **primary reviewer** in Office of Clinical Pharmacology, Office of Translational Sciences, supporting Division of Pulmonary, Allergy, and Rheumatology Products (DPARP); Division of Anesthesia, Analgesia, and Rheumatology (DAAAP); and Division of Nonprescription Clinical Evaluation (DNCE) in the CDER Office of New Drugs for 6 years.

Dr. Ying Fan obtained her Master degree in traditional Chinese herb in 2003 in Zhejiang Medical University, Hangzhou, Zhejiang, China, and received her PhD degree in pharmaceutical sciences (major) and statistics (minor) from Oregon State University in 2008.

This event is cosponsored by NTU Alumni Association DC Chapter (www.ntuaadc.org) and Chinese American Professional Association DC Chapter (www.capadc.org).