



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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## “Scientific Considerations for Establishing Bioequivalence of Generic Drug Products”

To be presented by

**Bing Li, PhD**

([bing.li@fda.hhs.gov](mailto:bing.li@fda.hhs.gov))

Expert Pharmacologist & Acting Deputy Director  
Division of Bioequivalence I, Office of Bioequivalence  
Office of Generic Drugs, CDER, US FDA

**Thursday, April 23, 2015**

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, 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, Commissioned Corp officers, 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, April 23, 2015.**

**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

Bioequivalence (BE) studies focus on demonstration of absence of difference in rate and extent between two products in the body. It serves as a major component in evaluating therapeutic equivalence (TE). TE products are expected to have the same safety and efficacy profiles, when administered under the conditions listed in the product labeling. For generic drugs, BE studies confirm the clinical equivalence between the generic and reference products. For new drugs, BE studies verify the clinical equivalence between different formulations and sometimes between different strengths. As such, BE is an integral part of development and regulations for both generic and new drugs.

This presentation focuses on the scientific and regulatory considerations for establishing BE of generic drug products. The approaches to determine BE, the appropriate BE study designs, and the bioanalytical and statistical considerations for BE studies will be discussed in details. Waivers for BE study will also be elaborated.

## Speaker's Bio: Bing V. Li, PhD

Dr. Bing V. Li is an **expert pharmacologist** and current serves as **Acting Deputy Director** in the Division of Bioequivalence I, Office of Bioequivalence, Office of Generic Drugs, Center of Drug Evaluation and Research, FDA. Her current responsibility is to direct and oversee the work of highly skilled staff of professionals in reviewing drug product bioequivalence studies submitted in Abbreviated New Drug Applications (ANDAs), develop guidelines applicable to the completion of reviews, and plan and manage the regulatory review operations.

Dr. Li has published over 50 papers, meeting abstracts, book chapters, and patents, and has been invited to give many presentations at national and international conferences. Dr. Li served as the **Vice President** of American Chinese Pharmaceutical Association (ACPA), and **chairs** of a number of FDA working groups. Dr. Li is the **winner** of numerous awards including Thomas Edison Invention Award, AAPS Outstanding Contributed Paper for Regulatory Sciences Awards, National Institute of Health Biotechnology Award, Bristol-Myers Squibb Triumph Award, FDA Center Director's Special Citation Award, and FDA Regulatory Science Excellence Award.

Dr. Li received her Ph.D. in Pharmaceutical Sciences from University of Wisconsin at Madison in 2001, and a bachelor degree in Medical Chemistry in 1990 in Beijing University, China. Prior to joining FDA in 2004, she was a **Research Investigator** at Bristol-Myer-Squibb.

**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 NTU Alumni Association at DC ([www.ntuaadc.org](http://www.ntuaadc.org)).**