



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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## “What FDA Expects in A Pharmaceutical Trial”

To be presented by

**Susan Leibenhaut, MD**

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Medical Officer

Office of Compliance

Center for Drug Evaluation and Research (CDER), US FDA

**Thursday, March 29, 2018**

**\*\*New venue\*\*:** **CCACC HQ, 9366 Gaither Rd. “1<sup>st</sup> Floor Music Room”, Gaithersburg, MD 20877**

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

6:20 – 8:50 PM – Program

8:50 – 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, current job-seekers, CCACC volunteers/employees/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, FAPAC members, CBA members, AAGEN members, NCARSQA members, OCA-DC members, AAMB members, ACAP members, DC Leaders Club members, BioTrain volunteers, and all Tai-Chi classes students in Metropolitan DC.

**Registration Deadline:** Please register by **Thursday noon, March 29, 2018.**

**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 8 onto Shady Grove Dr. Drive toward east and turn left onto Gaither Rd. The building is on your left after passing a stop sign.  
**By Metro rail:** Exit at the Red Line Shady Grove Station.

## Summary

The relevant regulations for Good Clinical Practice (GCP) were written in the 20<sup>th</sup> century. Now, in the 21<sup>st</sup> century, it is important to apply the basic principles and definitions of GCP from the previous century as well as to adapt to the changing technology, regulatory science, and policy to meet the needs of the current era of drug development and conduct.

This talk is a high level view of the history of the regulations and the relationship of the regulations to the science of drug development. I will present the factors that FDA considers in determining the quality of the conduct of a clinical trial as well as the actions and activities that study staff can perform in order to go “above and beyond” the regulations to ensure quality in the conduct of clinical trials. There will be a description of clinical inspections as well as metrics of the results of the inspections overseen by CDER/FDA.

## Speaker

Dr. Susan Leibenhaut received her B.S. from MIT and her MD from Albert Einstein college of Medicine. Dr. Leibenhaut practiced Internal Medicine in the Washington, DC area for 15 years before joining the FDA in 2000.

From 2000 to 2008, Dr. Leibenhaut was a **medical reviewer** in CBER for a wide variety of products, including cell and gene therapies with broad indications for adult and pediatric diseases including inborn errors of metabolism, cerebral palsy, atherosclerosis and osteoarthritis. Since 2008, Dr. Leibenhaut has been a **medical officer** in Office of Compliance, CDER where she has been active working with Office of New Drugs on clinical practice compliance issues concerning drug development and approval.



**Frances Kelsey, PhD, MD** received the President’s Award for Distinguished Federal Service from President Kennedy in 1962, the same year as the passage of the **Kefauver Harris Amendment** to the FD&C Act.

This event is cosponsored by Chinese Culture and Community Service Center, Inc. (CCACC, [www.ccacc-dc.org](http://www.ccacc-dc.org)), NTU Alumni Association DC Chapter ([www.ntuaadc.org](http://www.ntuaadc.org)), and Chinese American Professionals Association of Metropolitan Washington, DC ([www.capadc.org](http://www.capadc.org)).

