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)

"Challenges in Nonclinical Development of Inhalation Drug Products"

To be presented by

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Thursday, August 6, 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, 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, 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, August 6,*** *2015.*
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 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

There are special challenges in nonclinical development of inhalation drug products (IDP). These challenges are attributed to unique characteristics of IDP which are usually complex drug and device combinations. Nonclinical development of IDP generally requires animal inhalation toxicity studies (ITS) which have special requirements. The anatomy and physiology of the respiratory system in animals and humans also have their own special features. These factors contribute to the challenge of IDP development.

IDP generally requires special mechanical delivery devices and drug formulations. The creation and operation of each device (e.g., dry powder inhaler, metered-dose inhaler, nebulizer) involves sophisticated aerosol sciences and engineering. The formulation (e.g., dry powder, suspension, aerosol, solution) varies in dosage form and composition. The design and conduct of ITS in the laboratory requires special knowledge, skills, facilities, and equipment. The mode of administration of the test material may vary with animal species. It is often difficult to assess accurately the local and systemic exposures of animals and humans to IDP. The anatomy and physiology of the respiratory system in animals and humans have their own special features. There are responses unique to inhaled materials in animals and humans. Some responses may be species-specific. Each of the above features may affect the evaluation and interpretation of ITS findings in animals. Regulatory and research scientists involved in the nonclinical development of IDP should be aware of these challenges.

Speaker's Bio: Luqi Pei, DVM, MS, PhD

Dr. Luqi Pei is a **Senior Pharmacology and Toxicology Reviewer** at the US Food and Drug Administration (FDA). His department is the Division of Pulmonary, Allergy and Rheumatology Products at the Center for Drug Evaluation and Research (CDER). He conducts the nonclinical safety evaluation of drugs indicated for respiratory diseases, rheumatoid arthritis, and other diseases. He specializes in the nonclinical safety evaluation of inhaled drug products.

Prior to joining the FDA, Dr. Pei completed his **postdoctoral training** at the Lovelace Inhalation Toxicology Institute which is currently known as the Lovelace Respiratory Research Laboratories. Dr. Pei received his degrees of DVM from the Gansu University of Agriculture in China, MS from the Colorado State University, and PhD from the Texas A&M University. Dr. Pei was a **faculty member** at the Gansu Agriculture University and a **visiting scientist** at the Colorado State University. He also worked in a pharmaceutical company for a year.

This Biomed/Biotech SIG event is cosponsored by the Monte Jade Science and Technology Association of Greater Washington (www.MonteJadeDC.org) and NTU Alumni Association at DC (www.ntuaadc.org).