



American Society for Quality ([www.asq.org](http://www.asq.org)) – Washington D.C. and Maryland Metro, Section 509 ([www.asq509.org](http://www.asq509.org))

Biomed/Biotech Special Interest Group (SIG) Meeting

## “Regulation of Genetically Engineered (GE) Animals at the US FDA”

To be presented by

Brinda Dass, MPH, PHD, ALAT ([Brinda.Dass@fda.hhs.gov](mailto:Brinda.Dass@fda.hhs.gov))

and

Malini Wileman, PhD, RAC ([Malini.Wileman@fda.hhs.gov](mailto:Malini.Wileman@fda.hhs.gov))

Biologists

Animal Biotechnology Interdisciplinary Group (ABIG)

Office of the Director

Center for Veterinary Medicine (CVM), US FDA

**Thursday, September 13, 2012**

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

6:20 – 8:30 PM – Program

8:30 – 8:45 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, students, local interns, residents, postdocs, FDA Commissioner’s Fellows, and current job-seekers](#)

**Location:** Kelly’s Deli Conference Center, 7519 Standish Place, Rockville, MD 20855

**Registration Deadline:** Please register by **Thursday noon, September 13, 2012.**

**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 Car:** 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 train:** 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:

The Animal Biotechnology Interdisciplinary Group (ABIG) at FDA CVM analyzes data and information provided by sponsors of genetically engineered (GE) animals to assess their safety and efficacy as defined by the Federal Food Drug and Cosmetic Act. ABIG uses a risk-based, weight of evidence approach to characterize the hazards posed by the recombinant DNA (rDNA) construct used to develop each GE product. We will briefly describe this hazard characterization process and FDA's regulatory authority related to GE animals.

## Presenter's Bio:

### Brinda Dass, MPH , PhD, ALAT

Brinda has a PhD in Cell and Molecular Biology from Texas Tech University Health Sciences Center and an MPH from the University of Maryland. Her areas of expertise are animal models of disease, preclinical drug testing for childhood cancers, RNA biology, clinical trial management and epidemiology. She is a part of the Animal Biotechnology Interdisciplinary Group (ABIG) at FDA CVM where she assists with regulatory and policy matters regarding genetically engineered animals. She has wide ranging expertise in regulating a variety of GE animal species using the weight of evidence risk based approach adopted by ABIG. Prior expertise includes graduate teaching and research, animal colony management, and clinical trial site related activities.

### Malini Wileman, PhD, RAC

Malini has a PhD in Biomedical Sciences from Texas Tech University, and a postdoctoral fellowship in gene regulation at Johns Hopkins University. Prior to joining the FDA, Malini was a **Senior Manager** and **Study Director** at BioReliance, managing day-to-day operations designing and conducting viral clearance and cleaning validation studies evaluating the ability of manufacturing processes to produce biologic products safe for use in humans. At the agency, Malini has been involved in the review of submissions for genetically engineered (GE) animals while also working on agency policy issues on the regulation of GE animals.