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)

"FDA's Question-Based Review (QbR): A Risk-Based, Pharmaceutical Quality Assessment Tool"

To be presented by

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and

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Product Quality Reviewer
Office of Generic Drugs (OGD)
OPS, CDER, FDA

Thursday, December 5, 2013

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, MJ-DC members, CAPA-DC members, CCACC volunteers/employees, veterans, senior citizens, teachers, students, interns, residents, postdocs, FDA Commissioner's Fellows, and current job-seekers

Location: Kelly's Deli Conference Center, 7519 Standish Place, Rockville (Derwood, for GPS users), MD 20855

Registration Deadline: Please register by ***Thursday noon, December 5****, 2013.*

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 with its entrance opposite to the left side of 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:

FDAs Office of Generic Drugs (OGD) developed and implemented question-based review (QbR) for the Chemistry, Manufacturing, and Controls (CMC) evaluation of Abbreviated New Drug Applications (ANDAs, i.e., generic drug applications) in 2006. QbR provides a structured framework that follows the ICH common technical document (CTD) format for the submission of relevant information in the application. QbR was found to enhance the quality, effectiveness, and focus of regulatory assessment.

Currently, FDA is engaged in revising the QbR template to facilitate a patient-centric, risk-based quality assessment and is also exploring implementation of the QbR approach for the review of New Drug Applications (NDAs). The revised QbR focuses on quality standards for drug substance and drug product, product and process design, and facility considerations. This talk will provide an overview of QbR and discuss future related initiatives.

Presenter's Bio:

Sharmista Chatterjee, PhD

Dr. Sharmista Chatterjee is the **CMC Lead** for QbD (quality by Design) in the Office of **New Drug Quality Assessment** (ONDQA) at the FDA. She is currently serving as the **technical lead** for the FDA-EMA QbD pilot and as a **co-chair** for IFPAC 2014. Her other responsibilities include mentoring and training reviewers in assessment of QbD-based applications, providing consults for review of QbD-based applications, supporting development of review practices and policies associated with QbD-based new drug applications, and also supporting QbD-related research initiatives within the office. Sharmista received a BS in Chemical Engineering from Indian Institute of Technology and a PhD in Chemical Engineering from Iowa State University. Prior to joining the agency in 2006, she spent around 10 years in industry. Her industry experience was primarily in process development and modeling in diverse industries that included energy, consumer goods, food and pharmaceuticals.

Jennifer A. Maguire, PhD

Dr. Jennifer A. Maguire is a **Product Quality Reviewer** in the FDA CDER's OGD. She has served as a QbD **liaison** within OGD. She is also a member of the working group that is developing a QbR system for the future **Office of Pharmaceutical Quality** (OPQ) to be used by both generic and innovator applicants. Her other responsibilities include hiring and training new reviewers and responding to controlled correspondence submitted by industry to OGD. Jennifer has a BS in Chemical Engineering from the University of Virginia and a PhD in Industrial and Physical Pharmacy from Purdue University. She has over 10 years of combined experience in the scientific research, academic, and regulatory arenas. Jennifer started her career working in Chemical Engineering R&D at Merck & Co., Inc. where she developed and scaled up synthetic processes from the lab to the pilot plant to manufacture drug substance. She then joined Schering-Plough Research Institute in Pharmaceutical Product Development where she led the manufacturing of clinical and stability supplies of a novel drug product for cancer. Prior to joining FDA in 2010, Jennifer obtained her doctorate degree by specializing in vaccine formulation with aluminum-containing adjuvants to optimize clinical performance.

This Biomed/Biotech SIG event is cosponsored by the Monte Jade Science and Technology Association of Greater Washington (www.MonteJadeDC.org) and the Chinese American Professionals Association of Metropolitan Washington DC (www.capadc.org).