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

Biomed/Biotech Special Interest Group (SIG) Meeting

"Nanotechnology and Its Application in Innovative Medical Countermeasure Development"

To be presented by

Guilin "Gary" Qiao, DVM, PhD

Sr. Pharmacologist/SME

Joint Medical Science and Technology Office (JSTO)

Defense Threat Reduction Agency (DTRA)

US Department of Defense

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Thursday, February 23, 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 for non-ASQ members to cover pizza/drink cost;**
Free: ASQ Members, 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, February 23****, 2012.*

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 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:

Based on publically available information, this presentation will summarize the past history, present status and future trend of nanotechnologies related to biomedical research and medical product development. General definition, classification, characteristics, potential applications, opportunities and risk of namomaterials and of the most recent nanotechnologies will be discussed.

Well known to all, medical product performance in terms of quality, safety and efficacy in general, and end user suitability for chemical and biological defense in particular, can be largely improved per dose formulation and manufacture technology innovations. Defense medical countermeasures (MCMs) including small molecular drugs, biotech-based medical products and biologics are particularly relevant for improved delivery. Targeted and/or controlled drug delivery has been an important tool in achieving certain performance criteria of medical products in industrial R&D pipelines to gain greater likelihood of regulatory approval and improved market shares. A so-called SMART (Sensing, Multi-phased, Aimed, Responding Transport) drug delivery system concept is being developed by DTRA. General discussion of each aspect of a SMART delivery system and more importantly an innovative integration of those into a multipurpose system or platform technology, which can be tailored to serve various purposes, will also be discussed. Traditional nanomaterials such as liposomes and polymers, novel bioparticles, such as phase-based and viral-like particles (VLPs) versus hard nanoparticles, such as engineered carbon nanotube (CNT) and quantum dot are compared as potential MCM delivery system components. Scientific challenges, logistic considerations, and regulatory hurdles are also explored regarding MCM development and acquisition either for general hospital use or for counterterrorism/defense application.

Presenter' Bio: Guilin "Gary" Qiao, DVM, PhD

Dr. Guilin "Gary" Qiao has over 25 years of experience in lab research, FDA regulatory review, defense program/acquisition management, and university teaching in federal agencies and academia both in US (90-Pres) and China (86-90). He earned his DVM (82), MS (85, PK) and PhD (89, PK-PD) in Pharmacology and Toxicology. His professional interest has been focusing on drug ADMET, pharmacokinetic-pharmacodynamic (PK-PD) modeling, dermal toxicology, drug delivery, and defense R&D program management. As a ***Sr. Pharmacologist***, a ***Sci and Tech Manager (STM)*** and a ***Subject Matter Expert (SME)*** in pharmacology/toxicology, Dr. Qiao has been severing DTRA in medical portfolio regulatory compliance assessment, pipeline management, acquisition program management and new defense initiative establishment.

Dr. Qiao, as the COR/GOR (Contracting/Granting Officer's Representative), is a DoD Level III certified (the highest) STM, Level I certified Program Manager, and a member of DoD Acquisition Corps. Prior to his DTRA tenure, he worked as a ***pharmacologist*** in FDA/CVM (01-06), a ***Team Leader*** in CDC/NIOSH (98-01)***, an Adjunct Associate Professor*** at West Virginia University (99-06), a ***Research Assistant Professor*** (95-98) and a ***Postdoc*** fellow (90-95) at North Carolina State University. He conducted regulatory review of new animal drug applications while led a couple of FDA research and regulatory guideline drafting projects, directed NIOSH lab studies on dermal exposure assessment and modeling, and taught graduate courses and supervising PhD students at WVU and NCSU. He served as a Review Panelist for grant applications to DoD/Army/AIBS, and an Add-Hoc reviewer for domestic and international government agencies (FDA, NIH, OECD, etc), journal or book publishers. He was an Associate Editor of an Online Defense Journal, along with full memberships and leadership positions in many professional organizations, such as AAPS, SOT, AACT, AAVPT, CRS, and AGT. Dr. Qiao has been leading organizations, creating new specialty sections for professional societies (SOT/DTSS, SOT/AACT), chairing committees, and organizing workshops. He secured over $5M research funding and published over 30 peer-reviewed academic papers/book chapters prior to 2001 when he started his regulatory review and acquisition management career.