



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>)

“US Postmarket Safety Surveillance - A Medical Device Perspective”

To be presented by

Tahseen Mirza, PhD, MBA
(tahseen.mirza@fda.hhs.gov)

Deputy Director

Office of Surveillance and Biometrics (OSB)
Center for Device and Radiological Health (CDRH), US FDA

Tuesday, December 15, 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, NCARSQA 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 **Tuesday noon, December 15, 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

The speaker will provide an overview of the surveillance and post-market activities carried out by the US FDA to ensure the safety and effectiveness throughout the lifecycle of medical devices. The speaker will discuss how the main components of the surveillance system comprising of mandatory reports (Medical Device Reports), voluntary reports (MedWatch reports), hospital-based reports (Med Sun), and “522 post-market surveillance studies” are managed. The process for the management and detection of adverse event signals will also be elaborated.

Speaker’s Bio: Tahseen Mirza, PhD, MBA

Dr. Tahseen Mirza is an accomplished scientist with over 20 years of industrial and regulatory experience in the areas of medical devices and pharmaceuticals. He holds a PhD in Pharmaceutical Sciences from the University of Cincinnati and MBA. In his current position, he is the **Deputy Director** in the FDA/CDRH Office of Surveillance and Biometrics (OSB). The office is responsible for timely evaluation of medical device adverse events for signal identification and ongoing surveillance, as well as support for compliance, premarket evaluation, and other CDRH programs. It is also responsible for statistical and epidemiological analysis of clinical data to evaluate device safety and effectiveness for premarket evaluation and postmarket surveillance.

Prior to joining CDRH, Dr. Mirza served as a **Division Director** of the CDER/Office of Manufacturing and Product Quality’s (OMPQ) Division of Policy, Collaboration, and Data Operations (DPCDO). His responsibilities included management of Fields Alert Reports (FARs), MedWatch Quality reports, Incidences (cases in which death or injury is involved and the risk to public health is unknown), and Drug Quality Sampling and Testing program. He was also responsible for policy and guidance development for the office. Prior to joining OMPQ, Dr. Mirza was the **Deputy Director** of the Division of Product Quality Research (DPQR), within the Office of Pharmaceutical Science’s (OPS) Office of Testing and Research (OTF). Before joining the FDA, he spent close to 2 decades in the pharmaceutical industry. His last position in the private sector was as **Director** in the Technical R&D department of Novartis Pharmaceutical Corp, East Hanover, NJ. He has also worked in various capacities for Aventis (Sanofi Aventis), Merial (Merck/Aventis), and the United States Pharmacopeia (USP).

During his career, Dr. Mirza has led groups of chemists and PhD scientists in various R&D and QC/QA departments and is well versed in both early and late phase product development. He has enabled the transfer of manufacturing processes and analytical methods globally between R&D and manufacturing and contract manufacturers. He has lectured and trained industry and FDA scientists in Manufacturing Science, Biopharmaceutics, and Dissolution. He has co-authored more than 30 research articles. He has moderated national and international conferences and workshops on variety of topics such as drug release, dissolution, QbD and PAT. Dr. Mirza is the **founding Chairman** of the American Association of Pharmaceutical Science (AAPS) focus group, In Vitro Release and Dissolution.

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).