



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

Biomed/Biotech Special Interest Group (SIG) Meeting

“FDA’s Device Case for Quality”

To be presented by

**William C. MacFarland, MS, MBA &
ASQ CQE, CBA, CSQE, CSSBB, CMQ/OM, CRE**

Director, Division of Enforcement B

Office of Compliance

Center for Device and Radiological Health (CDRH)

US Food and Drug Administration (FDA)

(WILLIAM.MACFARLAND@FDA.HHS.GOV)

Thursday, February 14, 2013

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

6:20 – 8:30 PM – Program (intermission at 7:40 pm)

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, MJ-DC Members, veterans, senior citizens, 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 user), MD 20855

Registration Deadline: Please register by **Thursday noon, February 14, 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:

The FDA's medical device Case for Quality is a joint effort between the Office of Regulatory Affairs (ORA) and the Center for Devices and Radiological Health (CDRH). The ORA is the leading office for all FDA field activities and provides FDA leadership on imports, inspections and enforcement policies. The CDRH assures that communities have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products, while facilitating medical device innovation by advancing regulatory science and providing efficient regulatory pathways.

The Case for Quality promotes device quality through more focus on fulfilling user needs in addition to regulatory compliance; presenting more FDA-maintained data so that it can be used to assess and enhance device quality; and providing more engagement with stakeholders on the topic of device quality. This presentation will introduce the "Case for Quality" initiative and what is planned by ORA and CDRH in 2013.

Presenter's Bio:

MR. WILLIAM C. MACFARLAND is the Director, Division of Enforcement B, Office of Compliance, Center for Devices and Radiological Health (CDRH), FDA. This division's work relates to acting on violative medical device firms, removing defective devices from the market place, and reviewing quality/manufacturing information for high risk Class III devices to ensure they have sufficient quality. Mr. MacFarland has previously served in multiple other management positions within FDA/CDRH, as well as held many positions within the device industry and regulatory consulting industry before joining the Federal Government in 2004.

Mr. MacFarland received his BS in Electrical Engineering from Clarkson University, an MS in Biomedical Engineering from Case Western Reserve University, and an MBA from the University of Maryland. Currently he maintains a Professional Engineers license in Maryland. He is an ASQ senior member and holds certificates for ASQ Certified Quality Engineer, Certified Biomedical Auditor, Certified Software Quality Engineer, Certified Six Sigma Black Belt, Certified Manager of Quality/Organizational Excellence, and Certified Reliability Engineer.

This event is cosponsored by the Monte Jade Science and Technology Association of Greater Washington (www.MonteJadeDC.org).