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)

"Securing and Sharing the Worldwide Public Health Mission - Serving in the First US FDA Office in India"

To be presented by

Albinus (Abi) M. D'sa, PhD

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Deputy Director, India Office, US FDA

Thursday, July 9, 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, 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 ***Thursday noon, July 9,*** *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

In 2008, the US FDA was hit by two major contamination issues - Heparin and Melamine. The first pertained to drug contamination, and the second was due to pet food contamination that extended to milk products. It was the Heparin contamination issue that started the process of FDA considering opening offices overseas. Several offices were open, beginning with China leading the pack and followed by offices in India, Costa Rica, Mexico, Chile, South Africa, UK, Belgium, and Italy.

The reason for opening these offices was clear: Manufacturing of food and drugs had moved from the US to other countries around the world. China and India had become major suppliers of medicines, food, and devices for the US, and also for markets in the other parts of world. There was a need to develop a safety net to ensure that safe and effective medicines and food were supplied to the people in the US. The Congress passed a supplementary bill authorizing the foreign Offices to be opened so that the FDA could be close to the places where these products were manufactured, so that the quality, safety and efficacy of those products could be monitored to control the supply chain.

During the period of July 2009 to 2014, Dr. Albinus (Abi) D'Sa served as the Deputy Country Director for the FDA India Office. His experience with the opening of the first FDA Office in India will be discussed in this presentation.

Speaker's Bio: Abi M. D'Sa, PhD

Dr. Abi D'Sa returned to the FDA after serving for five years in FDA's India Office. Dr. D'Sa was the **Deputy Country Director** of from 2009 to 2014. While in India, he was responsible for managing the India Office and also served as the **lead** for all Pharmaceutical and Vaccine issues. During that tenure of his, HHS Secretary Sibelius and FDA Commissioner Hamburg visited India, and the Commissioner signed a "Statement of Intent" that paved the way for future collaboration with the Government of India in the area of Pharmaceuticals, Dietary Supplements, and Cosmetics.

Prior to that deployment, Dr. D'Sa served for 17 years at the Center for Drug Evaluation and Research (CDER), working in the areas of regulatory drug approval, inspection, and compliance. He brought a wide range of experience including formulating successful drug approval strategies and developing guidance for industry on complex drug quality and regulatory issues. Dr. D'Sa served as **Chairperson** of the Drug Product Technical Committee and as a **member** of the ICH Expert Working Committee and the Botanical Guidance Committee within CDER. Dr. D'Sa received his **doctoral degree** from the University of Missouri at Columbia, Missouri, in Organic Chemistry, and did a **post-doctoral research** at the National Institutes of Health, Bethesda, MD.

Accomplishments of Dr. D'Sa while in the FDA India office included: 1) Negotiated diplomatic positions and documents with the Indian Government, 2) Served as drugs expert for the Office in India, 3) Represented the US FDA to interact with regulatory counterparts in India, and 4) Wrote and supervised development of important analytical papers.

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).