



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

Biomed/Biotech Special Interest Group (SIG) Meeting

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## “US FDA Import Operations”

Presented by

**CDR Domenic Veneziano**

Director

Division of Import Operations and Policy

Office of Regulatory Affairs, US FDA

**Thursday, January 13, 2011**

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

6:20 – 8:20 PM – Program (a 10-min break at 7:30 pm)

8:20 – 8:45 PM – Door-prizes drawing; Networking

**Open to Public** - Free to [ASQ Members](#) (*Become a ASQ Member & Save*)

**\$5 for [non-ASQ members](#) to cover pizza/drink cost**

**Free to all [High/Middle/Elementary School Students](#)**

**Location:** Kelly’s Deli Conference Center, 7519 Standish Place, Rockville, MD 20855

**Registration Deadline:** For headcount purpose, please register by Thursday noon, January 13, 2011.

**Registration Website:** <http://www.asq509.org/ht/d/DoSurvey/i/35817>

**Question:** Please contact Dr. C.J. George Chang, Chair of Biomed/Biotech SIG; [gchang2008@yahoo.com](mailto:gchang2008@yahoo.com) or 240-793-8425 (cell).

### **Presentation Summary: “US FDA Import Operations”**

Commander Domenic Veneziano will provide an overview of FDA import operations and related regulatory and enforcement actions that FDA takes. The challenges that have been noticed related to the globalization of FDA regulated commodities will also be discussed. A Q&A session will follow afterward.

## **Speaker Biography:**

**CDR Domenic J. Veneziano ([domenic.veneziano@fda.hhs.gov](mailto:domenic.veneziano@fda.hhs.gov))**

**Director, Division of Import Operations and Policy**

CDR Veneziano has been the **Director** of the **Division of Import Operations and Policy, Office of Regulatory Affairs (ORA), US FDA** since March of 2005. He is responsible for providing direction, guidance, and leadership to all FDA district offices and senior agency officials related to import operations for FDA regulated commodities.

Domenic is a graduate of the University of Maine where he earned his Bachelors degree in Engineering. He began his FDA career in 1992, as an **Investigator** in the **New England District Office, Northeast Region, ORA**, where he conducted both foreign and domestic inspections and investigations.

In 1998, he accepted a position as a **Supervisor** in the **New England District Office** where he was responsible overseeing the Medical Device and Import programs. In August of 2003, CDR Veneziano accepted the challenge of establishing, staffing, and **directing** the **Prior Notice Center, ORA**, FDA's first 24/7/365 operation and since moved to the Metropolitan Washington DC area.

## **Directions to meeting venue: From I-270 (North or South bound):**

Take Exit 9A and exit from the first right exit.

Turn left (east) onto Shady Grove Drive.

Turn right (south) onto Rockville Pike (**Route 355**).

Turn left (east) onto East Gude Drive.

Turn left (north) immediately onto Crabbs Branch Drive.

Turn left (west) immediately onto Standish Place.

The first building on your right side is 7519 Standish Place; open parking. The conference room is on the first floor with its entrance opposite to the left side of 7519 building main entrance.