



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>)

“FDA Food Safety Modernization Act (FSMA) – The Vision and Challenges of Improving Food Safety”

To be presented by

Joseph A. Levitt, Esq

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Partner, Hogan Lovells, US LLP

Former Director, Center for Food Safety and Applied Nutrition, US FDA

Thursday, October 9, 2014

6:00 – 6:35 PM – Networking; Pizza/drink

6:35 – 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, 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, Commissioned Corp officers, and current job-seekers.

Location: Kelly’s Deli Conference Center, 7519 Standish Place, Rockville (Derwood, for GPS users), MD 20855

Registration Deadline: Please register by Thursday noon, October 9, 2014.

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

Following a series of high visibility outbreaks of foodborne illness from a variety of sources, in December 2010 Congress passed landmark legislation to improve food safety, which the President signed the first week of January 2011. The goal of this legislation is to shift the government's emphasis away from responding to problems after they occur, and towards greater attention on preventing such problems from occurring in the first place.

To do so, Congress embraced the scientific principles that had already been developed – called Hazard Analysis and Critical Control Points (HACCP) -- and implemented for specific food categories – meat, poultry, seafood and juice products. These same principles will now be applied across the entire food supply.

The major challenge lies in applying broad principles across a wide variety of food products and facilities, including a growing number of international facilities that export food to the U.S. The challenges are particularly significant for smaller companies and for the fresh produce industry which has never before had mandatory regulations from the FDA.

Speaker's Bio: Joseph A. Levitt, Esq

Mr. Joseph Levitt is a 25-year veteran of the U.S. Food and Drug Administration (FDA); he served as **Director** of FDA's Center for Food Safety and Applied Nutrition (CFSAN) for six years, from February 1998 through December 2003. Joe led successful efforts to modernize food safety regulation and enhance the security of the U.S. food supply. He also initiated a revitalization of FDA's nutrition program.

During his earlier FDA tenure, while in the Office of the Commissioner as the **chief of staff**, Joe helped streamline the new drug review process and launch the agency's food labeling initiative. Additionally, he served as **Deputy Director** for Regulations and Policy at the FDA's Center for Devices and Radiological Health (CDRH). He began his FDA career as a **staff attorney** in the Office of Chief Counsel.

Currently as a **partner** at Hogan Lovells US LLP, Joe counsels numerous food companies and trade associations in food safety, labeling and compliance matters and how to work effectively with the FDA. He is a recognized expert in the Food Safety Modernization Act (FSMA), including all phases of its development and implementation.

Joe has received a Top Tier ranking from Chambers for Food and Beverage lawyers. While at FDA, he received numerous honors and awards, including three Presidential Executive Rank Awards. More recently, Joe received the FDA Distinguished Alumni Award. Mr. Levitt received his bachelor's degree, magna cum laude, from Cornell University in 1975 and his J.D. degree, cum laude, from Boston University School of Law in 1978. Mr. Levitt was the recent past **Chairman** of the FDA Alumni Association for the past two years.

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).