



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

Biomed/Biotech Special Interest Group (SIG) Meeting  
(<http://www.asq509.org/ht/d/sp/i/31557/pid/31557>)

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## “ICH – Its History, Evolution, Achievements and Challenges”

To be presented by

**Justina A. Molzon, MS Pharm, JD**  
([molzonj@gmail.com](mailto:molzonj@gmail.com))

Former Associate Director for International Programs  
Office of Strategic Programs  
Center for Drug Evaluation and Research (CDER), US FDA

**Thursday, February 26, 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, 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, 7529 Standish Place, Rockville ([Derwood, for GPS users](#)), MD 20855

**Registration Deadline:** Please register by **Thursday noon, February 26, 2015.**

**Question:** Please contact Dr. C.J. George Chang, Chair of Biomed/Biotech SIG, ASQ509; [gchang2008@yahoo.com](mailto: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 International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), launched 25 years ago, is an unparalleled undertaking. ICH brings together the drug regulatory authorities of Europe, Japan, and the United States, along with the pharmaceutical trade associations from these three regions, to discuss scientific and technical aspects of product registration. It is ICH's mission to achieve greater harmonization in the interpretation and application of technical guidelines and requirements for product registration, thereby reducing duplication of testing and reporting carried out during the research and development of new medicines.

This presentation will provide background information on the history and process of ICH as well as modifications to the ICH process in terms of expansion of participants, outreach to other regions and countries, and efforts toward increasing the transparency of the ICH guideline development process.

## Speaker's Bio: Justina A. Molzon, MS (Pharmacy), JD

Justina Molzon is a **pharmacist and attorney**, and was a **commissioned officer** in the US Public Health Service. She recently retired from FDA's Center for Drug Evaluation and Research (CDER) and the position of the **Associate Director for International Programs**, Office of Strategic Programs, CDER, FDA. One of her primary responsibility was coordination of CDER's efforts related to the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). Capt. Molzon also coordinated CDER's activities related to the President's Emergency Plan for Aids Relief (PEPFAR) and was involved in technical outreach to the PEPFAR focus counties.

She received her BS (with honors and distinction) and MS in Pharmacy, with a concentration in pharmaceutics and pharmacognosy, from the University of Rhode Island and law degree from the Chicago-Kent College of Law/Illinois Institute of Technology. She is a **Fellow** in the American Society for Pharmacy Law, serving on its **Board** of Directors from 1989-1997. In 2008 she was **honored** with the US Public Health Service Mary Louis Andersen Leadership Award (pharmacy of the year) for extraordinary dedication and leadership in support of global public health. In 2009 she was **awarded** an exemplary service award by the Surgeon General of the United States for her international efforts, and in 2010 received a Distinguished Achievement Award from the University of Rhode Island College of Pharmacy. She is very grateful to have had the opportunity to work with international drug regulatory authorities in assuring the safety, efficacy and quality of pharmaceuticals worldwide.

**This Biomed/Biotech SIG event is cosponsored by the Monte Jade Science and Technology Association of Greater Washington ([www.MonteJadeDC.org](http://www.MonteJadeDC.org)) and NTU Alumni Association at DC ([www.ntuaadc.org](http://www.ntuaadc.org)).**