



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

Biomed/Biotech Special Interest Group (SIG) Meeting

**“Incorporating Risk Management into Quality Systems
– A Key Operation at the American Red Cross”**

Presented by

Boriana Cavicchia, MS

**Director, Quality Assurance, Div. Biomedical Services
American Red Cross**

Monday, December 13, 2010

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

6:20 – 8:30 PM – Program (a 10-min break at 7:40 pm)

8:30 – 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 Local [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 Monday noon, December 13, 2010.

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 or 240-793-8425 (cell).

Presentation Summary: “Incorporating Risk Management into Quality Systems – A Key Operation at the American Red Cross”

This presentation will use a key operation at the America Red Cross to discuss:

- The missions, key products, and operations of the American Red Cross
- The scope for the Biomedical Services division of the American Red Cross
- Definition of Risk Management according to ICH Q9 and Description of various risk management tools (FTA, FMEA, risk maps, etc.)
- How can Risk Management be applied to your operations according to ICH Q10

- Risk Management Principles in Failure Mode Effects Analysis (FMEA)
- FMEA ratings and Determination of Risk Priority Number (RPN) applied to temperature controlled distribution of blood components
 1. Map the process for assigning ratings for severity, probability of occurrence, and detection
 2. Describe (worst-case) shipping lane for FMEA
 3. Execute FMEA
 4. Calculate risk priority number
 5. Propose corrective and preventive actions (CAPA)
 6. Calculate %Reduction in risk priority number and evaluation new risks based on the preventive actions

Speaker Biography: **Boriana Cavicchia, MS**

Boriana Cavicchia is the **Director of Quality Assurance** at the Biomedical Services Division of the American Red Cross. She is responsible for providing quality assurance oversight related to **national procedures, the CAPA system, and acquisitions** at the American Red Cross.

Boriana has over 15 years of experience in quality assurance, validation, compliance, and analytical chemistry applied to biologics, pharmaceuticals, and medical devices. As a member of the Pharmaceutical Cold Chain Management Discussion Group, Boriana participates in writing and revising industry guidelines for supply chain management of health care products. She is also a member of the Parenteral Drug Association and the American Chemical Society. Boriana has a MS degree in chemistry from the George Washington University.

Directions to meeting:

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.