



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>)

“Survive Leaving a Federal Job - My Journey of Becoming a Consultant”

To be presented by

Jinjie Hu, PhD

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Senior Consultant, Biologics Consulting Group

Chair, International Network Committee, FDA Alumni Association

Thursday, June 22, 2017

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

6:20 – 8:45 PM – Program

8:45 – 8:55 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, NTMUADC members, CKUAADC members, NTHUAADC members, NJTUAADC members, CCACC volunteers/employees, FAPAC members, CBA members, AAGEN members, NCARSQA members, OCA-DC members, AAMB members, ACAP members, DC Leaders Club members, BioTrain volunteers, 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, June 22, 2017.**

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

Making a career change is not easy. But, you can do it!

Also, you will feel very proud of the transformation after you have done that!

Are you tired of working at the same position for a long time? Are you thinking of try a different career? Do you wish to take on some challenges before you think you get too old? Do you want to share your knowledge and skills with people who need them? But you have a perfect job that everybody wishes or you feel comfortable with. Whatever in your mind, you are not alone on this difficult topic.

As a previous FDA reviewer who went through the career transformation, Dr. Jinjie Hu will share her own experience of identifying the urge of changing in her career, the struggling process to decide leaving a permanent Federal job. The advice that she wished for before she left her previous job can help you to prepare better. She will also share her experience as a consultant including how she navigate the most difficult time on the new job and how to deal with the demanding that she didn't anticipate before. In addition, she will share her view of the needs in fast evolving global biomedical field.

Speaker's Bio: Jinjie Hu, PhD



Dr. Jinjie Hu is the **International Network Committee chair** of the FDA Alumni Association and a **senior consultant** working at Biologics Consulting Group. She has almost 12 years of experience with the Food and Drug Administration, Center for Biologic Research and Review. She was a **senior expert regulatory/scientific reviewer** for multiple analytes In Vitro Diagnostic Devices (IVD) products. She lead and chaired many review committees for 510 (k), IDE, PMA, IND and BLA. Dr. Hu's responsibility included reviewing CMC, analytical and clinical study data, and labeling. She also has extensive experience working within the Center offices and other Centers of the FDA in reviewing companion diagnostic products, combination products, and applications for Clinical Laboratory Improvement Amendments (CLIA) waivers.

As a trained **manufacturer facility reviewer** and **CGMP inspector**, she performed many pre-approval inspections of IVD manufacturing facilities. She also served CBER education planning committee and an **instructor** for CBER's Medical Device Training course for 4 years (2009-2012). She has been serving as **scientific advisor, dossier reviewer and manufacturer facility inspector** for the In Vitro Diagnostic Pre-Qualification Program at WHO since 2009. As the **chair** for the International Network Committee of the FDA Alumni Association, she provides leadership to collaborate with developing and emerging regulatory agencies for regulatory capacity building and training.

Jinjie received her B.S. in Cell Biology from Beijing Normal University and her Ph.D. in Comparative Pathology from University of California, Davis, followed by postdoctoral fellowship at National Institute of Allergy and Infectious Diseases at the NIH.

This event is cosponsored by NTU Alumni Association DC Chapter (www.ntuaadc.org) and Chinese American Professional Association DC Chapter (www.capadc.org).