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)

"Challenges and Opportunities in Developing Biologics and cGMP Operations Excellence in China"

To be presented by

Edward Wang, PhD

Z&W BIO Consulting LLC

(ewangcba@gmail.com)

Thursday, February 6, 2014

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, teachers, students, interns, residents, postdocs, FDA Commissioner's Fellows and Sigma Xi members, MJ-DC members, NTUAADC members, CAPA members, CCACC volunteers/employees, CBA members, 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, February 6****, 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 with its entrance opposite to the left side of 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:

It is predicted that Chinese pharmaceuticals market will be the second largest in the world besides US by 2020. Two challenges remain in Chinese pharmaceutical market: availability and affordability, and there are two complementary routes for biologics registration in China: import license and local manufacturing.

China's regulatory requirements and restrictions are limiting factors for importing blockbuster biologics, not requiring manufacturing in China, to the Chinese market. For example, humira and herceptin were approved in China 4-8 years later than US; for synagis, it has been approved in the US for 15 years, but China has yet started. On the other hand, for the NDA applications (typically used by local companies in China), the GMP operations including engineering practices are the limiting factors. Even through most of the product development can potentially be performed outside China, there are basic but limiting requirements, e.g., the "Process Validation" lots (3 lots) have to be manufactured in China. Therefore, each local biopharmaceutical company will have to have their own GMP Biologics facility. From both technology and cost prospective, those regulatory requirements put local biopharmaceutical companies in very challenging positions.

China needs an open platform to enable companies to discover therapeutic products better, faster and more efficiently. The speaker will share his experience of recent practice in China creating an open-access platform for R&D Innovation, specifically in developing biologics and GMP operations excellence.

Presenter's Bio: Edward Wang, PhD

Dr. Edward Wang is the **Vice President & Member** on the Board of Directors of Chinese Biopharmaceutical Association (www.CBA-USA.org). He has 20 years of combined experience in the biopharmaceutical and medical device industries, and is specialized in cGMP Manufacturing Technical Operations with expertise in aseptic processing of bulk drug substance handling and fill&finish operations.

Dr. Wang was the first to implement automatic fill and finish production line for National Cancer Institute at SAIC-Frederick, MD, during 2001-2004. Since then, Edward has provided consulting services, as a **founder** of an independent consulting business, Z&W Bio Consulting LLC, to commercial pharmaceuticals operations leading the release of dozens of US Drug Shortage Medicines. He contributed more than 50 clinical lots of innovative antibodies/vaccines for phase I/II trials, and is active in pharmaceutical engineering industry focusing in cGMP compliance from facility design, construction, validation as well as manufacturing operations.

Prior to the Z&W Bio Consulting, Dr. Wang worked at AERAS Global TB Vaccine Foundation. In that capacity, he was part of an **engineering team** that was responsible for a cGMP facility process engineering design, construction, and cGMP validation. With the project management and team-building ability, he has received numerous professional awards and training certificates. After serving as an **independent consultant** in 2012 at WuXiAppTec Biopharmaceuticals Co., Ltd. China (www.wuxiapptec.com), Dr. Wang was given the responsibility to lead WuXiAppTec's biologics service in 2013 as **Vice President** of Technical Operations.

Edward has published over 50 peer reviewed papers, has three patents granted for biotechnology products, and serves on review committees for various biotech journals. Dr. Wang came to the US from China Academy of Science 27 years ago; he earned a doctorate degree from Helsinki University of Technology, Helsinki, Finland, with a major of Biotechnology and a minor in Microbiology.

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).