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

Design, Construction & Operation of Multi-Product cGMP Biopharmaceutical Facilities

To be presented by

Edward Wang, PhD

Bio-processing Consultant

Thursday, September 15, 2011

6:00 – 6:20 PM – Networking; Pizza/drink
6:20 – 8:30 PM – Program (a 10-min intermission at mid point)
8:30 – 8:50 PM – Door-prizes drawing; Networking

Online Registration site: http://www.asq509.org/ht/d/DoSurvey/i/35817

Open to Public - **$5 for non-ASQ members to cover pizza/drink cost; Free to ASQ Members, students, local interns, postdocs, and FDA Commissioner's Fellows**

Location: Kelly's Deli Conference Center, 7519 Standish Place, Rockville, MD 20855
Registration Deadline: Please register by ***Thursday noon, September 15****, 2011.*
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 Car: 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 train**: 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: "Design, Construction and Operation of Multi-product Manufacturing Facilities"

Biopharmaceutical manufacturing is highly regulated. Establishing bio-manufacturing capacity begins with a "**Base of Design**" which includes "**User's Requirement Specifications (URS)**" in compliances with regulatory guidelines.

Pre-design delineates the investment objectives, and knowing the process in detail is the base of technical parameters for facilities and equipments specification. While in the early stage of design, a "**Master Validation Plan**" with regulatory authority's critic and comments is always a plus, which has big impact of overall success of the project/program. **Operation** of a cGMP biopharmaceutical facility is complex, and involves managing not only manufacturing personnel but also quality manufacturing systems. There are many elements in the operation critical for the successful delivery of releasable finished biologics products.

This presentation will cover the following topics:

- How to get a cGMP facility design started?
- How long will the construction take and how much will it generally cost?
- What does a cGMP facility look like?
- How to operate a cGMP facility in order to produce added value?

Examples of the speaker's prior experience working with countries in the East will also be discussed.

Presenters' Bios: Edward Wang, PhD (ewangcba@gmail.com)

Dr. Edward Wang has over 15 years of pharmaceutical processing and manufacturing experience in **process development** of therapeutics and vaccine products. He has worked within three cGMP facilities, manufacturing over ten types of **viral vaccines** and **therapeutic monoclonal antibodies**, as well as **recombinant proteins** which were in various phases of clinical development. Dr. Wang's areas of expertise include protein and viral vaccine downstream purification process integration, pilot facility engineering, clinical manufacturing management, and technology transfer. In the past 8 years, his main focus has been on downstream process development, technology transfer and cGMP manufacturing implementation. His work included **pilot plant cell culture harvest clarification**, using Tangential Flow Filtration (TFF) technology, and **vaccine and MAb purification process**, using AKTA Pilot Chromatography Systems.

Dr. Wang has hand-on experience with **sterile bulk drug substance** (API) handling and vialing operations in **Class 100 clean rooms**. He was the first to implement the automatic fill and finishing production line for NCI at SAIC-Frederick. His **aseptic process** skills includes the accomplishment of tens of thousands of vial-filled products, which led to more than 30 clinical lots released for clinical trials at various development stages. In his managerial capacity at the cGMP pilot plant operation, his contribution led to the delivery of finished products of the **Recombinant Protective Antigen (rPA)** of the anthrax vaccine. Edward has published over 50 peer reviewed papers and has had three patents granted with biotechnology product development. He has served on review committees for various biotech journals, and is currently active in **Bio-process Consulting**.