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

Biomed/Biotech Special Interest Group Meeting

"Biomedical/Biotechnology Opportunities and Challenges in Taiwan and China"

Presented by

Keith Chan, PhD

(kchan@globoasia.com)

Professor, Graduate Institute of Intellectual Property
College of Commerce, National Chengchi University, Taiwan, ROC
Director of International Affairs
GloboAsia LLC and Revico Inc.

"Research and Development of a Hepatitis E Vaccine"

Presented by

James Wai Kuo Shih, PhD

(jwshih@xmu.edu.cn)

Professor of Microbiology
National Institute of Diagnostics and Vaccine Development
Xiamen University, Xiamen, Fujian, China

August 6, 2009 (Thursday) Evening

6:00 PM – Networking and Pizza and soft drink with a door prize

6:20 – 9:10 PM – Program

9:10 – 9:15 PM – Door-prize drawing and networking

Open and free to the public

Location:
Kelly's Deli Conference Center, 7519 Standish Place, Rockville, MD 20855

Driving directions:

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 conference room is on the first floor with its entrance opposite to the left side of building main entrance.

For headcount purpose, please register by *Thursday noon, August 6, 2009.*

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

For registration problems or further information contact **Dr. George Chang**, Co-Chair of Biomed/Biotech SIG, at gchang2008@yahoo.com or call **240-793-8425**.

A. Presentation Summary:

Biomedical / Biotechnology Opportunities and Challenges in Taiwan and China

The operational strategy of developing biomedical/biotechnology products is to maximize the profit of that product from lab bench to market withdrawal while take full advantage of the intellectual rights as well as food & drug laws and regulations during the whole product development cycle (the whole value chain). Often time, there is no need to develop the whole technology into product and then sell them to the consumers. Biotech players and developers can create commercial and profitable opportunities during any stage of the product life cycle value chain. Pending on the type of technology and core competence of the company, any one can contribute and take advantage of available opportunities and cut into the value chain as a player. There have been drastic changes in the field of biomedical and biotechnology over the last several years in Asia Pacific region. This presentation will update you on the recent development in Taiwan and China.

Research and Development of An Hepatitis E Vaccine This presentation will entail some background of HEV infection, the pre-clinical studies, and Phase I & II clinical development results, and the on-going work in China of the Phase III clinical trial.

B. Speakers' Bios:

Dr. Keith Chan obtained his PhD degree in Pharmaceutics from Univ. of Minnesota in 1980, and is currently **professor at the Graduate Institute of Intellectual Property, College of Commerce, National Chengchi Univ**. and adjunct Professor and Advisor at the Research Center for Drug Discovery, National Yang Ming Univ. in Taipei, Taiwan, ROC. He also serves as **Director of International Affairs, GloboAsia LLC and Revico Inc., Rockville, MD, USA** and as advisors for several research institutes and regulatory agencies in Asia, as well as consultants for several pharmaceutical firms in Asia and in the US. He is a co-founder of GloboMax LLC. He had served as adjunct Professor at the School of Pharmacy, University of Maryland at Baltimore and at the National Board of Advisor, College of Pharmacy, Univ. of Minnesota at Minneapolis since 1984. He worked fro Ciba-Geigy Corporation in Ardsley, New York for 15 years and held various senior and management positions. He also worked for the US FDA as Division Director at the Office of Generic Drugs for 3 years. He was elected as fellow of the American Association of Pharmaceutical Scientists (AAPS) in 1995 for his scientific accomplishments on drug absorption in humans. He had organized numerous workshops and conferences in China, Taiwan, Hong Kong, Singapore, and Korea, serves as a scientific advisor for many regulatory agencies in Asia, and have successfully in assisted many Asian companies in their technology transfers and licensing deals to and from US as well as numerous regulatory submissions to the US FDA. His most recent accomplishment was to lead a Taiwan company to complete a new drug development program starting from IND up to human Phase II trial and then subsequently out-licensed it to a public US biopharmaceutical company.

Dr. James Wai Kuo Shih graduated from Vanderbilt University, Nashville, TN and worked for Georgetown University and FDA Biologics prior to his joining NIH Clinical Center. At NIH, he was a Senior Investigator and Chief of laboratory study at the Infectious Disease Section, NIH Blood Bank for 23 years. He retired in 2006 and moved to China and serves as a **Professor of Microbiology, National Institute of Diagnostics and Vaccine Development, Xiamen University, Xiamen, Fujian, People Republic of China**.

Dr. Shih was one of the critical founders/the Clinic Director for the Pan Asian Clinic (of Chinese Culture and Community Service Center (CCACC)) for the Montgomery County, MD.