



**Sino-American Pharmaceutical Professionals Association
Greater Philadelphia Chapter (SAPA-GP)**

2008 Member Conference

Quality by Design & Biostatistics

**May 10th (Saturday), Holiday Inn Conference Center
432 Pennsylvania Avenue, Fort Washington, PA 19034 (Phone: 215-643-3000)**

Online registration: <http://www.sapa-gp.org/mconf/reg8.htm>

The pharmaceutical Quality by Design (QbD) is a systematic approach to product and process design and development. To facilitate the implementation of QbD, a pilot program launched by FDA for new drug application (NDA). Nine original NDAs and two supplemental NDAs were accepted. As of Sept 19, 2007, seven of these NDAs had been submitted, of which six were approved and one was under review.

To better understand what are QbD and the relationship to PAT and statistics, what are Lean Six Sigma and the best practice in process and control for improved quality and efficiency from development to manufacturing, leading experts from FDA and major pharmaceutical companies were invited to address the challenges and implementation of the "Quality by Design & Biostatistics.

Through the presentation and interactive discussions, you will have an unrivalled opportunity to hear from and network with industry practitioners, academic experts and technology providers.

You can not afford to miss this pharmaceutical industry event if you work in the areas:

- ◆ QA/QC
- ◆ Analytical development
- ◆ Technology
- ◆ R & D
- ◆ Operations
- ◆ Pharmaceutical Development
- ◆ Sales/Marketing
- ◆ Consultancy
- ◆ PAT Team
- ◆ Process Development & Control
- ◆ Chemistry/Chemical Engineering
- ◆ General Management
- ◆ validation

Program

Quality by Design & Biostatistics

<u>TIME</u>	<u>TOPIC & SPEAKER</u>
8:30 a.m.	Registration / Continental Breakfast
9:00 a.m.	Welcome and Opening Remarks, Conference Chair Laura Hong, MD., PhD Sr. Research Biochemist, Merck & Co
9:05 a.m.	SAPA-GP President Remarks Zhongda Zhang, Ph D. Principal Scientist, Biomol International
9:10 a.m.	Keynote speech: Quality by Design: Bridging the Gap between Drug Development and Manufacture Timothy Schoffld, MS. Senior Director, Merck & Co.
9:50 a.m.	Keynote speech: Pharmaceutical Quality by Design: Product and Process, Development, Understanding, and Control Lawrence X. Yu, PhD. Director, FDA
10:30 a.m.	Networking Coffee Break
10:45 a.m.	From concept to practice: Implementation of QbD in late-phase pharmaceutical R&D and commercial manufacturing Weiyong Li, Ph D. Research Fellow, J&J
11:20 a.m.	Pharmacovigilance: Principle, Practice and Perspective Jie Chen, MD., PhD. Associate Director, Merck & Co
11:50 a.m.	Some Theoretical and Practical Aspects of QbD/PAT Implementation in Pharmaceutical Development Jun Hung, Ph D. Principal Scientist II, Wyeth
12:20 p.m.	Networking Lunch
01:20 p.m.	Keynote Speech: Randomized Clinical Trials: Advances and Challenges James Hung, Ph D. Director, CDER, FDA
02:00 p.m.	Application of Lean Six-Sigma Methodologies to Pharmaceutical Basic Research: an Example of Improving Turnaround Time for Bioanalysis James Yergey. Ph D. Senior Director, Merck & Co.
02:40 p.m.	Quality by Design in Process Development and Analytical Science

Sarah Chen, PhD. Investigator, GSK

03:15 p.m. **Networking Coffee Break**

03:30 p.m. Statistics: Use it and Love it
Jason Liao, Ph D. Associate Director, Merck & Co

04:05 p.m. Clinical Trial Paradigm in Drug and Vaccine Development
Ivan Chan, Ph D. Senior Director, Merck & Co.

04:50 p.m. Closing Remark of Conference Co-Chair
Lee Kang, PhD, MBA. Sr. Director, Perrigo

05:00 p.m. Close of Member Conference