



**Sino-American Pharmaceutical Professionals Association**  
**Symposium on Regulatory Affairs**

**Saturday, May 22, 2010**

9:00 AM – 7:30 PM

**Robert Wood Johnson Medical School**  
675 Hoes Lane West - Piscataway, NJ 08822  
Main Lecture Hall Auditorium

**Symposium Co-Chairs**

**Jane Xiang, Ph.D. and Jiwen Chen, Ph.D.**

**9:00 – 11:45 AM Session I**

**The Changing Regulatory Landscapes – Opportunities and Challenges**

**Jane Xiang, Ph.D., Jiwen Chen, Ph.D.**

9:00 - 9:15

**Opening Remarks**

Jianji Wang, Ph.D., SAPA President-Elect

9:15 - 10:00

**“An Overview of the Current Global Pharmacovigilance System with Particular Attention to China”**

Stephen L. Klinecicz, D.O., M.P.H., J.D., Vice President, Benefit Risk Management, J&J

10:00 - 10:45

**“New Initiatives and Trends at the FDA”**

Lawrence Yu, Ph.D., Director of Regulatory Sciences, FDA

11:00 - 11:45

**“Regulatory Perspectives on Clinical Trials: Current Regulations and Emerging Issues”**

Derek Zhang, Ph.D., Vice President, Regulatory Affairs and Clinical Pharmacology, Frontage Laboratories, Inc

**12:00 – 1:00 PM Lunch break**

**1: 00 – 2:45 PM Session II**  
**Managing Differences in Regulatory and Compliance Expectations**  
**Lee Kang, Ph.D., MBA, Lian Huang, Ph.D.**

- 1:00 - 1:25      **“Challenges and Opportunities for Chinese Companies in Regulated Markets (US)”**  
Lee Kang, Ph.D., Director, Asia Pacific Quality Operations, The Perrigo Company
- 1:25 - 1:50      **“Compliance Requirements for Imports to US Market: Chinese Companies Inspections”**  
Charisse Green, Investigator, Dedicated Foreign Drug Cadre, FDA
- 1:50 - 2:15      **“Identification of Chinese Pharmaceutical Manufacturing Partners and Due Diligence: US Sourcing Perspective”**  
John Budzinski, Ph.D., Managing Director, Global Pharma Sourcing, LLC
- 2:15 - 2:45      **Panel Discussion**  
Speakers and Victoria Wei, Ph.D., J&J

**2: 45 – 3:00 PM Break**

**3: 00 – 4:45 PM Session III**  
**Bridging Careers from Research Labs to the Regulatory Field**  
**Xin Du, Ph.D., Jerry Huang**

- 3: 00 - 3:25      **“Preparation before Applying for a Job in the RA Field”**  
Xin Du, Ph.D., Director, Regulatory CMC Biologics, Worldwide Quality & Compliance, Bristol-Myers Squibb Company
- 3:25 - 3:50      **“Being a RA Professional: Duties and Responsibilities - Perspective from the Industry”**  
Lois Hinman, Ph.D., Novartis Pharmaceuticals Corporation, Global Head Biologics Oversight & Strategic Projects
- 3:50 - 4:15      **“Being a RA Professional: Duties and Responsibilities - Perspective from the FDA”**  
Chiang Syin, Ph.D., Lab Chief - FDA/CBER/OCBQ/DMPQ/BII
- 4:15 - 4: 45      **Panel Discussions**  
Speakers and Jerry Huang, Ph.D., Pfizer

**5:00 – 5:30 PM Break**

**5:30 – 7:30 PM Social Hour & Dinner**

(including 30minutes presentation on Opportunities in Wujiang)

Jianji Wang, Ph.D., Baoguo Huang, Ph.D.

**Symposium Sponsors**

**Municipal Government of Wujiang, Jiangsu**

**GeneWiz**

**Symposium Organizing Committee**

*Jane Xiang, Xin Du, Lee Kang, Lian Huang, Jerry Huang, Mingliang Zhang, Baoguo Huang, Kevin, Chen, Helena Feng, Yan Xia, Jisong Cui, Jiangji Wang, Jiwen Chen, Xiaoying Zhang*

**Please register at [www.sapaweb.org](http://www.sapaweb.org)**