SAPA 2006 Great Philadelphia Conference

美中医药开发协会 2006 大费城年会

Saturday, June 17, 2006

Science Center, Montgomery County Community College, 340 Dekalb Pike, Blue Bell, PA 19422

Sino-American Pharmaceutical Professionals Association, Greater Philadelphia Chapter (SAPA-GP) (**www.sapa-gp.org**)

21st Century Innovation & Globalization of Medicine Development

二十一世紀医药开发的创新和国际协作

Registration (*www.sapa-gp.org*) ***Pick up Name Tags, Continental Breakfast, and Networking – 7:30 to 8:30***

8:30-11:40	**Session 1:** (英文)	***Current Challenges, Innovations, & Globalization of Medicine Development***
Moderator:	**Li Yan**	
8:20-8:30	**Li Shi**	**Conference Chair Open Remark**
8:30-9:00	**Robert R. Ruffolo**	President, WW Research & Development, Wyeth Pharmaceuticals, SVP, Wyeth Co.
9:00-9;30	**Peter Honig**	Executive VP, WW Regulatory and Product Safety, Merck & Co., Inc.
9:30-10:00	**Ronald Krall**	Senior VP, WW Development, Chief Medical Officer, GlaxcoSmithKline
10:00-10:20		**Tea and Coffee Break**
10:20-10:50	**Sanjay Batra**	Vice resident, R&D Pharmaceuticals, Johnson & Johnson
10:50-11:20	**Catherine Bonuccelli**	Vice President of External Scientific Affair, AstraZeneca
11:20-11:40	**Li Shi & Jian Li**	**SAPA-GP 2006-2007 President and EC Operation Team Transition**
11:40-1:00	**Lunch Break**	
1:00-4:30	**Session 2:** (英文)	***Current Trend in Global Pre-Clinical and Clinical Research, Development, and Collaboration***
Moderator:	**Haisong Tan**	
1:00-1:25	**Mark Engel**	President and CEO, Excel PharmaStudies
1:25-1:50	**Samantha Du**	General Manager, Hutchsion Medipharma Limited, China
1:50-2:15	**James Cai**	Vice President, Research and Development, AstraZeneca China
2:15-2:40	**Zili Li**	Director, Clinical Operation, Merck Research Laboratories, Merck & Co., Inc.
2:40-2:50		**Tea and Coffee Break**
2:50-3:15	**XiaoChang Dai**	General Manager, Sino-American Kunming Baker Norton Pharmaceutical Co., LTD
3:15-3:40	**Le Sun**	President and CEO, Welson Pharmaceuticals, Inc.
3:40-4:05	**Nathan Zhang**	CEO, Laviana Corporation, Beijing Research Center
4:05-4:30	**Ling Chen**	Manager General, Guangzhou Institute of Biomedicine & Health
1:00-4:30	**Session 3:** (中文)	***Current Advances in Drug Discovery, Research, Development, and Regulation in China***
Moderator:	**Zhongda Zhang**	
1:00-1:25	**Wei Dong Yin**	Presidnet and CEO, SinoVac Biotech Pharm
1:25-1:50	**Guozhong Rui**	Director, International Technology Exchange and Transfer Center, SFDA (invited)
1:50-2:15	**Qiang Zhang**	Vice President, School of Pharmaceutical Science, Peking University
2;15-2:40	**Jason Jin**	Senior VP, Global Business Development, President, MaxyBio Corporation for SBC speaker.
2:40-2:50		**Tea and Coffee Break**
2:50-3:15	**Zegong Zhang**	Vice Director, Beijing Biopharm Center (invited)
3:15-3:40	**Ming Jiang**	General Manager, Dalian Bio & Pharm Industry Park Development Co. (invited)
3:40-4:05	**Song Li**	President and CEO, Frontage Laboratories
4:05-4:30	**Gangqiang Cai**	Director of Guang Zhou Municipal, Science & Technology Bureau

4:00-5:30 **Session 4:** (中文) ***Panel Discussion:***

1. What should be the strategies for US companies to benefit from the rapid growth of China pharmaceutical industry?

2. What should be the strategies for Chinese pharmaceutical industry to move into the international market place in the next one and two decades?

All speakers who will stay to the end and joined by:

Ling Su (moderator)	Director, Medical and International Pharma Development, Roche Pharmaceuticals Ltd, China
Ling Chen (moderator)	M.D., Ph.D. Director-General, Guangzhou Institute of Biomedicine & Health, CAS
Ruyi He	Manager, FDA

5:40-9:00	**Session 5:** (中文)	***Banquet: Pearl River Night Banquet*** (珠江之夜晚宴招待会) **(Serve Western Food)**
Moderator	**Li Shi**	
	Li Jian	**Open Remark**
	Yuanhe Lin	Executive Vice Mayor of Guangzhou City
	Yuelun Liu	Director General, Guangzhou Development District (GDD)
	Delegates from	**Beijing, Shanghai, Guangzhou, Dalian, Shangdong, Yunnan, and Hainan**

美中医药开发协会 2006 大费城年会 会前及会后专题学习研讨班

Doubletree Guest Suites Plymouth Meeting
640 W. Germantown Pike
Plymouth Meeting, Pennsylvania 19462-1003, USA
Tel: 1-610-834-8300
Fax: 1-610-879-4242
Website: http://www.doubletree.com/en/dt/hotels/index.jhtml?ctyhocn=PHLGHDT

当代新药研发是一个花费昂贵，耗时漫长的复杂过程。一个新药从基础研发至走向市场，需要花费新药开发公司 8 亿至 12 亿美元及十到十二年的時間。在未来的五到十年中，中国医药工业面临着走向国际市场的巨大压力和挑战。长期以来以传统原料药生产及国内市场为目标的中国制药工业，在新药研发和竞争国际市场方面尚缺乏经验。为了改变这种局面，国内医药工业的领导者和决策层须对国际现代医药研发过程有一个全面的了解，对国际著名医药企业的运作有一个充分的认识。为了向国内医药同行介绍现代新药研发的全貌，美中医药开发协会將特别举办当代新药研发学习研讨班。学习研讨班将涵盖新药研发中的各个步骤，例如基础研究，先导物选取，临床前研究，制剂设计，代謝及毒性评估，生产流程设计和研发，質量分析测试，穩定性研究，临床試驗，工業生产，报批申请，以及销售管理和市場開發等。

学习研讨班详细内容（课程将以中文讲授）

1. 会前研讨班 2006 年六月 16 日 1 pm - 5 pm：Chair: Lee Kang
   “在美国食品药品监管局 FDA 注册申請 DMF/CMC/IND 和 NDA/BLA 申报策略”
   Draft topics that will be discussed
   美国食品药品监管局新药研发监控管理法規在公司研发和生产中的功效和影响
   DMF/CMC/IND/NDA/BLA/CTD 文件的准备和申报的准备策略
   申报前和美国食品药品监管局的交流讨论会
   准备美方(FDA or Partner)对(中国)企业在申报前及合同签署前的检查

2. 会后研讨班 2006 年六月 18 日 9 am - 5 pm：Chair: Hua Zhong and Chang Bai
   “当代国际医药研究，开发，制剂，质量控制，临床研究，生产，注册申請及上市的全过程”

新药研究
   新药研发中的基础研究：研发的启动、进程，和完成
   药物设计、筛选和优化中的药物化学：基本原理和实践
临床前开发
   药物的可开发性，剂型设计和流程优化
   药物的吸收分布代谢和毒理研究中的主要问题和技术：药物分子的内禀质量
   药物安全性评估在新药研发中的作用
   药物化学生产流程的研发，作用和挑战
临床研究
   分析化学在药物生产流程研发和质量控制中的作用
   药物稳定性测试以及药物产品的質量分析
   新药研发中的临床研究综述
新药申报 (may be jumped over since it will be covered by June 16 workshop above)
   监控管理法規在新药研发和申报中的功效和影响
   医药化学，生产，控制 (CMC) 文件的准备和申报的准备策略
新药生产
   药物的工业生产制备和工艺流程：竞争由此开始
新药上市
   美国市场上的新药行销的策略和實踐