

Sino-American Pharmaceutical Professionals Association-Greater Philadelphia Chapter (SAPA-GP)
1st Generic Drug and Biopharmaceutical Conference

April 15, 2006, 8:00 am – 5:30 pm

Best Western at Towamencin, 1750 Sumneytown Pike, Kulpsville, PA 19443

Generic drugs in the US now account for about 12 percent of the nation's \$250 billion a year in drug spending and more than 53 percent of prescriptions filled according to IMS Health, a company that tracks the industry. It also predicts that the percentage will exceed 65 percent within four years as several blockbuster drugs go off patent. Express Scripts, which manages pharmacy benefits for many insurers, estimates that the figure could be 70 to 75 percent by 2010.

The desire for health care cost management also creates an ever-increasing need for affordable medicines, and the availability of generic products for health benefits has become evident. In response to an increased growth in consumer desire and interest in generic products, the need for sound scientific and regulatory foundations in the development and manufacture of generic pharmaceuticals has been recognized.

During the last ten years, the generic pharmaceutical industry has undergone significant changes due to technology advancement (in both small molecules and biomolecules) and globalization. There are several questions would emerge as the trend continues, and they need to be answered by scientists, regulators, and marketers in pharmaceutical industry. These questions are, but not limited to, where the new product and technology come from (small molecules vs. biomolecules), what the new technology platforms are, how regulators regulate new technology in bio-generics, how regulatory agencies handle soaring number of applications, and how outsourcing opportunities in China can aid the generic drug development.

SAPA-GP is organizing this one-day conference to provide a venue for learning about generic drug development and attempting to understand the current trend of small molecule and bio-generics. Several veteran speakers from generic and biopharmaceutical industries, patent law firms, and sourcing agencies and suppliers will discuss the new trend and technology in development, manufacturing, regulations, and commercialization of small molecule generics (AM session) and specifically opportunities/challenges the new biotechnologies can bring about (PM session). It's unlikely any of these questions and issues can be answered with any degree of certainty, but eventually these issues will have to be incorporated into the Pharmaceutical Industry's strategic planning process. We welcome your participation in this meeting.

Organization Committee: Zhongda Zhang, Li Yan, Lee Kang, Hua Zhong, Jiwen Zhang, Jian Li and Li Shi

Best Wishes

Li Shi, President, SAPA-GP
Jian Li, President-elect, SAPA-GP

Note from the Organization Committee

The conference will be held at 8:00 am -5:30 pm on April 15, 2005. The meeting registration fee will be \$30 for SAPA members and \$40 for non-members. The fee will cover the meeting cost, a breakfast, two tea/snack breaks, and a buffet lunch (American food served buffet style). Due to limited number of seats available (120), we will provide online registration only starting on March 15, 2006 at www.sapa-gp.org. If your company is interested in being a sponsor for this conference, please feel free to contact: Zhongda Zhang at zhongda7@yahoo.com

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- 7:40-8:00 **Registration** (picking up name tags)
8:00-8:10 **Opening Remark:** Zhongda Zhang, Ph.D.

Morning Session: *Generic Drug Symposium*
Strategy and Challenges of Product Development, Regulation, and Marketing

Generic Drug Symposium Chairs:
Lee Kang, Ph.D., MBA, Sanofi Aventis, and Hua Marlon Zhong, Ph.D., J&J

- 8:10-8:55 Generic drug challenges in paragraph IV submissions and product development
life cycle, future market projection
Prakash Kulnarni, Ph.D., Sr. Director, TEVA, USA
- 8:55 - 9:40 Generic drug bioequivalence issue and IVIVC challenges
Harold Boxembaum, Ph.D., Principal Consultant, Arishel
- 9:40-10:25 China sourcing issue for generic industry in the US market
James R. Bruno, Director, Chemical and Pharmaceutical Solutions
- 10:25-10:45 **Break**
- 10:45-11:30 IP challenges for generic drug development and case studies
Stephanie Hsieh, Patent Attorney, Davidson, Davidson & Kappel, LLC,
- 11:30-12:15 Generic drug regulations and new FDA regulatory review initiatives
Lawrence Yu, Ph.D., Director, OGD, CDER, FDA
- 12:15 -1:00 **Lunch Break**

Afternoon Session: *BioPharma Symposium*
Modern Biopharmaceutical Development and BioGenerics

Biopharm Symposium Chairs:
Li Yan, M.D., Ph.D., Centocor R&D, Inc., J&J, and Jiwen Zhang, Ph.D., Wyeth

- 1:00-1:45 Monoclonal antibody therapeutics and manufacturing
Rich Siegel, Ph.D., VP of Pharmaceutical Development, Centocor R&D, Inc.
- 1:45-2:15 Biological R&D Platform for Contract Services in China
Liangzhi Xie, Ph.D., CEO, Beijing Sino CellTech
- 2:15-3:00 FDA Regulation of Biologics and Biosimilars and Biofollow-ups
Ronald Falcone, Ph.D., Senior Director, Centocor R&D, Inc.
- 3:00-3:20 **Break**
- 3:20-4:00 Virus Like Particle Based Vaccine Against Pandemic Avian Influenza
Rahul Singhvi, Ph.D., President and CEO, Novavax, Inc.
- 4:00-4:40 SunwayBio and its Oncolytic Virus
Fang Hu, Ph.D., President, Sunway, Inc.
- 4:40-5:20 **Panel Discussion**
- 5:20 **Closing Remarks by SAPA-GP President:** Li Shi, Ph.D.