

Biopharmaceutical Development – From Discovery to Commercialization

Report on the 12th CBA Annual Conference

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The Chinese Biopharmaceutical Association (CBA), USA, successfully held its 12th Annual Conference at the University of Maryland Shady Grove Conference Center in Rockville Maryland on June 2-3, 2007. The theme of the conference was **Biopharmaceutical Development: From Discovery to Commercialization**. With a total of 8 sessions ranging from *Clinical Development* to *Path to Regulatory Approval*, the conference virtually covered all the important steps in the process of biopharmaceutical development. More than 30 well-established scientists, entrepreneurs and representatives from government agencies delivered presentations and shared experiences in their career development with the audience. The conference attracted over 300 conference attendees from China and all over the United States. Toucan Capital and 28 other companies and organizations generously supported the conference.

On the morning of June 2, 2007, Dr. Dan Zhang, the 12th CBA president, and Ms. Yuling Li, the president-elect and the 12th CBA annual conference chairperson, started the conference with a brief opening remark. In addition to a warm welcome to the conference attendees, Ms. Li also thanked all the CBA members, volunteers, and sponsors whose contributions made the 12th CBA Annual Conference possible.

The conference started with three keynote presentations related to three critical stages, including discovery, development and growth, in the *Clinical Development*. The first keynote speaker, Dr. John W. Daly, scientist emeritus from the National Institute of Diabetes and Digestive and Kidney Diseases, the National Institutes of Health, started the first session with a presentation titled “Natural Products: Past, Present, and Future Role in Drug Discovery.” As Dr. Daly pointed out, biologically active natural products have a significant impact to the development of new therapeutic agents and provide invaluable research probes: the plant kingdom has provided a wide array of therapeutic agents; bacteria and fungus have provided many antimicrobials and antifungal; marine sources currently are yielding a further rich harvest of potential therapeutic agents; amphibian skin has proven to be a remarkable source of antibiotic peptides, steroidal bufadienolides, and a variety of alkaloids. The audience members were amazed to hear how much one could learn from the nature and how much the nature could offer.



Following Dr. Daly's presentation, Dr. Paul S. Lietman, professor from the Johns Hopkins University, delivered the second keynote presentation. With a title of “Clinical Research and Early Drug Development in Asia,” Dr. Lietman shared his knowledge on drug development and experience in conducting clinical research in Asia with the audience. As the founding director of the research

and education division for Johns Hopkins Singapore, Dr. Lietman knew well what kind of roles academic clinical research units could play in the drug development, especially in the early phases of drug development. Dr. Lietman believed there should be many great opportunities for a small number of academic institutions to lead the way by forming model clinical research units that strictly adhere to the guidelines of the International Conference on Harmonization guidelines for drug development in China.



Dr. Whaijen Soo, the third keynote speaker, ended the first session with a presentation on “The Third Dimension of Growth Strategy for Global Biopharmaceuticals: Geographic Reach to China and Beyond.” With over 20 years of clinical development experience in many countries including the United States and China, Dr. Soo had a lot to offer in terms of conducting clinical studies in different countries. According to Dr. Soo, the entry strategy for China can be fundamentally different from those used for other countries because of different epidemiology, different R&D environment, and different regulation rules in China. However, what has learned from other countries including Russia and east Europe can be used in China as well as India. Dr. SOO also predicted there would be many great research and business opportunities related to prostatic cancer in China in the near future.

The second session, ***Process Development and Manufacturing***, consisted of 2 presentations: “Points to Consider for Expedient Completion of a GMP Compliant Biologics Facility” delivered by Mr. Robert J. Valdes from the Human Genome Sciences (HGS) and “Single Use Technologies for Today’s Biopharmaceutical Production” presented by Dr. Xuemin Liu from the Pall Corporation. With more than 15 years of experience in the biotechnology industry, Mr. Robert J. Valdes, an associate director at the HGS, had a lot of first-hand experiences in designing and building GMP compliant biologics facilities. Mr. Valdes introduced the history of HGS and the process of building HGS’ Large Scale Manufacturing (LSM) facility, which is one of the few facilities in the world that have 20,000-liter cell culture reactors. Because of reduced downtime for cleaning and improved equipment lead time, single-use technologies are increasingly attracting the biopharmaceutical industry’s interest. Dr. Liu, marketing manager at the Pall Corporation, informed the audience the advantages and disadvantages of single-use technologies. Dr. Liu also illustrated how single-use products were used to improve production efficiencies in drug development process.

In the era of globalization, many pharmaceutical companies are outsourcing their R&D and clinical studies to China. Cheap labor, huge talent pool, and favorable government policies also attract many smaller biopharmaceuticals as well as individuals’ interest. ***Toucan Forum on Biopharmaceutical Business in China***, the third session of the conference, was specially designed to meet CBA members’ interest in the pursuit of success in the Chinese biopharmaceutical industry. This session included two presentations and one panel discussion. Ms. Linda L. Powers, managing director and co-founder of the Toucan Capitals, and Dr. Jintao Zhang from the Medicilon Inc in China shared their first-hand experience in conducting business in China with the audience. In her presentation, “Clinical Trials in China

by Very Small US Biotech Companies: Opportunities and Challenges,” Ms. Powers pointed out the success factors for small US biotech companies (less than 12 employees) to conduct clinical studies in China. These success factors include

- Plan early and communicate frequently
- Build up a strong local operation team
- Plan for extensive monitoring
- Set up study coordinator and quality assurance
- Stay updated with the SFDA’s regulations.

Dr. Jintao Zhang introduced Medicilon’s experience of providing preclinical drug discovery services in China.

Ms. Powers and Dr. Zhang’s presentations aroused many questions and concerns from the audience. One of the biggest concerns was whether the foreign companies were taking advantage of the underprivileged Chinese patients and how to protect Chinese patients who participate in the clinical trials sponsored by foreign pharmaceutical companies. The panelists appeared to be well aware of the concerns, but they did not think that the foreign companies were solely taking advantage of the Chinese citizens because first of all, when conducting clinical trials in China, the foreign companies were using international standards which were higher than the current Chinese standards; second, the Chinese government was taking actions to protect the Chinese patients; third, many Chinese patients, who otherwise would not have access to treatments, benefited from the international standard care offered in the clinical trials. The panel and the audience also discussed issues related to IP protection and biological products in China.

Following Toucan Forum, Dr. Andrew Chang, Senior director at PharmaNet Consulting, and Dr. Dan Zhang, CEO of Fountain Medical Development Ltd, introduced the corresponding regulations of biotechnological and biological products in the United States and in China in the fourth session, ***Path to Regulatory Approval***. In this session, the speakers overviewed the FDA and SFDA approval processes and addressed the differences between the FDA and SFDA. According to Dr. Dan Zhang, there are many advantages of conducting clinical studies in China in addition to low cost and fast patient enrollment. For example, the NDA approval process is less than 6 months. As far as IP protection, Dr. Dan Zhang thought that China was catching up very quickly. Following Dr. Zhang’s presentation about regulatory in China, Dr. Chang, one of the foremost experts in recombinant and naturally derived protein products who served in the US FDA more than 11 years before joining the PharmaNet Consulting, discussed the FDA’s approval process.

The fifth session of the day, ***Genome Integrity and Cancer***, was co-organized by the Baltimore-Washington D.C. Chapter of the Society of Chinese Bioscientists in America (SCBA). Four scientists from the National Institutes of Health and Johns Hopkins University presented their most recent research results. Dr. Chuxia Deng talked about “BRCA1 and Beyond: Genome Integrity, Aging, Cancer and Targeted Therapy;” Dr. Weidong Wang explained “DNA Damage Response Network of Fanconi Anemia and Breast Cancer Proteins;” Dr. Ie-Ming Shih introduced “Analyzing Ovarian Cancer Genome – from Gene Discovery to Therapeutic Targets;” Dr. Paul Liu reported the “Leukemogenic Mechanism by CBFβ-MYH11, a Fusion Gene Generated by the Chromosome 16 Inversion in Human AML.”

The evening session was specially designed for relaxing and networking. The session included cocktail reception, CBA banquet, 2007 CBA Brilliant Achievement Award ceremony, featured presentation, and announcement of CBA presidential election. Sipping drinks, tasting food, and chatting with friends and colleagues, conference attendees and media representatives indulged into the relaxing atmosphere of the cocktail reception and banquet.



Started in 2003, the CBA “Brilliant Achievement Award” was established to recognize individuals who made a significant impact to the biopharmaceutical industry. Previously, the awards have been presented to Dr. Kenneth Fong, founder and former CEO of Clontech; Dr. Nancy T. Chang, founder and CEO of Tanox; Dr. Frederick Frank, vice chairman and director of Lehman Brothers, Inc.; and Dr. Paul Schimmel, member of the Academy of Sciences and the Ernest and Jean Hahn professor at the Skaggs Institute for Chinese Biology at the Scripps Research Institute. The 2007 CBA Brilliant Achievement Award was presented to Dr. Jing Lou, CEO and President of 3SBio Inc. to recognize his contribution to the Chinese biopharmaceutical industry. In his award lecture, Dr. Jing Lou shared the successful story of 3SBio, the biggest Chinese biopharmaceutical in China. Dr. Lou also overviewed the opportunities and challenges in the Chinese biopharmaceutical industry. According to Dr. Lou, currently, there are many great opportunities for CROs, consolidation of medicine distributors and retailers, contract manufactures, and biopharmaceutical R&D in the Chinese biopharmaceutical industry. Along with the opportunities, Dr. Lou also pointed out the challenges in the Chinese biopharmaceutical industry ranging from the imperfect SFDA regulation to the under developed Chinese biopharmaceutical market.



Mr. An Pu Ruo, renowned novelist and VC investor, delivered a featured presentation focused on the life of Haigui. As the author of <<Taming the Chinese Fire>>, Mr. An Pu Ruo was quite popular among overseas Chinese Scholars. His presentation, “Haigui, What do You Expect and What Are You Expected in China?” provoked laughter and thought.

After the featured presentation, Dr. Yingxian Xiao, past CBA president (2003 – 2004) and member of CBA board of directors, announced the 2007 CBA presidential election results: Dr. Lin Sun-Hoffman, Sr. Patent Attorney at the Applied Biosystems, Applera Corporation, was elected the new president-elect, Ms. Yuling Li became the new CBA president, and Dr. Dan Zhang would continue to serve the CBA as the immediate past president.

The conference on June 3 started with the *Young Scientists Forum*, a unique session devoted to the CBA student and postdoctoral members from the local universities. The session started with “Collaboration and Information Sharing to Translate Science into Applied and Marketable Technology: Achieving Professional Leadership in the Biotechnology Industry through the Chinese Biopharmaceutical Association” presented by Mr. Colonel Jayson Sawyer, chief of the Analysis and Assessment Team in the Department of the Army. Through graphic demonstration and case studies, Mr. Colonel revealed the secret to “profession fitness” - social network. In the following panel discussion, the audience and the panelists discussed a wide spectrum of issues related to networking. The panelists not only stressed the critical roles of networking played in their own career but also taught the young scientist how to network. The panelists also shared their personal stories in terms of professional growth and success. Dr. Rudy Domingo from GlaxoSmithKline said that when you found your passion, success would follow. However, if you wish to change a career, you have to be flexible to be able to learn new knowledge and gain experience, and sometimes you have to be willing to start from the very beginning, as Ms. Claire Driscoll, director of Technology Development at the Human Genome Research Institute addressed. Ms. Yuling Li, Senior director from the HGS talked about how to deal with career ups and downs. Ms. Yuling Li encouraged the young scientists always try their best and never give up no matter how disappointing the situation might appear to be.

The session “*From Discovery to Clinical Development*” included two presentations: “Selection and Development of New Biologics for Clinical Development” by Dr. Adam Bell, director of CoGenesys and “The Story of How a NIH Small Grant Became a Multimillion Dollar Clinical Success” by Dr. Chun Li from the University of Texas, M.D. Anderson Cancer Center. Dr. Bell addressed the key scientific and medical criteria used to identify areas of unmet need and new product opportunities, whereas Dr. Li shared an amazing story of how he and his team developed a water-soluble polymer-paclitaxel conjugate worth multimillion dollars by using a small NIH grant.

Dr. Shi-min Fang, director of the New Threads Chinese Cultural Society, delivered a closing featured presentation on “The Hope and the Hype: Oversea Returnees and Chinese Science.” As a pioneer in the fight against false science, Dr. Fang was well respected among the conference attendees. His presentation in Chinese not only provoked laughter but also aroused many questions and concerns ranging from strategies used to disclose false science to how to deal with revenges.

After Dr. Fang’s presentation, Ms. Yuling Li, CBA president (2007-2008) closed the conference with a brief summary. Overall, the one and a half days conference was very successful in terms of providing a platform for CBA members to learn, network, and grow; advancing collaboration among Chinese-American biopharmaceutical professionals; and promoting technology transfer and business collaboration between China and the United States.