SAPA 2006 Great Philadelphia Conference
美中医药开发协会 2006 大费城年会

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

Saturday, June 17, 2006
Science Center, Montgomery County Community College, 340 Dekalb Pike, Blue Bell, PA 19422

Robert R. Ruffolo, Jr. (Senior Vice President, **Wyeth**)
Peter Honig (Executive Vice President, **Merck**)
Ronald Krall (Senior Vice President, **GSK**)
Sanjay Batra (Vice President, **Johnson & Johnson**)
Catherine Bonuccelli (Vice President, **AstraZeneca**)
Mark Engel (President and CEO, **Excel PharmaStudies,** China)
James Cai (Vice President, **AstraZeneca**, China)
Wei Dong Yin (Presidnet and CEO, **SinoVac Biotech Pharm**.)
William Goebel (Vice President, **CimQuest**)
Rui Guozhong (Direct, **SFDA**, China)
Zhang Zegong (Vice Director, **Beijing Biopharm Center**)
Samantha Du (General Manager, **Hutchsion Medipharma**)
Honggang Bi (CEO, **Frontage**, US-China)
XiaoChang Dai (General Manager, Sino-American **Baker Norton Pharm.**)

Registration: **www.sapa-gp.org**

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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 and Awards

11:40-1:00 **Lunch Break**

1:00-4:30 **Session 2:** (英文) ***Current Trend of 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.
2:40-3:50		**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.
3:40-4:00	**Nathan Zhang**	CEO, Laviana Corporation, Beijing Research Center*
4:00-4:10	**Lingwen Zeng**	Investigator, Guangzhou Institute of Biomedicine and Health, Chinese Academy of Sciences
4:10-4:30	**William Goebel**	Vice President, CimQuest*

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)
3:40-4:00	**Honggang Bi**	CEO, Frontage Laboratories, US and China
4:00-4:10	**Gangqiang Cai**	Director of Guang Zhou Municipal, Science & Technology Bureau
4:10-4:30	**Wendy Pan**	Morgan Lewis & Bockius

4:30-5:40 **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
Mark Tang	President, World Technology Venture

6:00-9:00 **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	Conference Chair Open Remark
Yuanhe Lin	Executive Vice Mayor of Guangzhou City
Yuelun Liu	Director General, Guangzhou Development District (GDD)

Note: Some speakers and timing subject to possible replacements or change

SAPA 2006 Great Philadelphia Conference

21st Century Innovation & Globalization of Medicine Development

(not in exact order of final presentations)

8:30-11:40 **Session 1:** (英文) ***Current Challenges, Innovations, & Globalization of Medicine Development***

Peter Honig, M.D., M.P.H., Executive Vice President, Worldwide Regulatory and Product Safety, Merck Research Laboratories, Merck & Co., Inc.

Challenges, opportunities, new approaches of discovery and development of the treatment and prevention of human diseases with impact of globalization effort. There are significant challenges facing the discovery and development of new approaches for the treatment and prevention of human diseases. There are also significant opportunities to address unmet medical needs based upon new discoveries in science and technology. Focused efforts to decrease cycle times, increase productivity and improve the probability of success are being implemented across the industry. Global collaborations at all stages of research and discovery are favorably impacting the process and provide the potential to significantly impact the industry's ability to deliver on our mission.

Robert R. Ruffolo, Jr., Ph.D., President, Research & Development, Wyeth Pharmaceuticals, Senior Vice President, Wyeth Corporation

21st Century Innovation and Globalization of Medicine Development – Wyeth's New Clinical Development Paradigm. R&D costs are growing dramatically and disproportionately to both budget increases and actual output of R&D. Annual inflation exceeds 12%, but actual budget increases are running well below this level. A 2003 Bain and Company study indicated the level of investment is $1.7 billion from a laboratory discovery to new product launch. The regulatory climate globally is also changing, and growing more unfavorable. Regulatory agency and patient expectations for safety must always remain high, but the industry needs to determine whether expectations are reaching unrealistic and even unachievable heights:

- Approval times continue to lengthen
- The number of clinical trials and corresponding number of patients per clinical trial are increasing,
- R&D cycle times in all phases are increasing
- Success rates are decreasing for drugs in all phases of clinical development – particularly Phase 2 clinical trials. Recent CMR data show that only 20% of Phase 2 candidates proceed successfully into Phase 3. A new paradigm in clinical research is necessary.
- Despite denials from Regulators, there is growing regulatory conservatism in the "post-Vioxx" era, as evidenced by increased numbers of "approvable and non-approval" letters (compared to "approval" letters), more "black box" issuances and a record low number of new drugs approved in 2005.

During 2005, Wyeth Research & Development undertook a number of initiatives to address this situation. A ***"Clinical Development Model of the Future"*** initiative began in 2005 and is being launched in 2006 to reverse some of these trends seen in clinical development. Some of the key initiatives being are:

- A "Learn and Confirm" paradigm to replace the classical Phase 1-4 clinical trials
- Greater utilization of Adaptive Clinical Trials
- Early Clinical Development Centers (i.e., Phase 2 "Supercenters") located in areas of high patient density
- A "24x7" global clinical work model
- Shifts in Global Patient Recruitment

We believe that these initiatives will, at least in part, reverse the current negative trends in global clinical development and provide an advantage in innovation and globalization well into the 21st century.

Ronald Krall, M.D., Senior Vice President, World Wide Development, and Chief Medical Officer, GlaxoSmithKline

Medicines for Patients: Medicines are responsible for a significant portion of the health we enjoy today, and promise even more to society tomorrow. There have been and continue to be major scientifically based advances in our ability to identify drug targets, leads, and candidates, and to recognize pharmacologic activity in humans. But our approach to developing drugs remains an exercise in demonstrating efficacy and safety in populations, despite the fact that most drugs are used to treat individual patients. Today we can begin to study medicines in ways that will make them more relevant and useful to individual patients. In this talk I will discuss approaches to development that might generate data more relevant and meaningful to individual patients.

Catherine M. Bonuccelli, MD, Vice President, External Scientific Affairs, AstraZeneca Pharmaceuticals

AstraZeneca: In China, For China: AstraZeneca has become the leading multinational company in China by building a network of marketing and sales offices, a manufacturing site and fostering clinical research. AstraZeneca was the first multinational pharmaceutical company to include China as an area for large-scale international multi-center trials and establish a clinical research center there. With China's rapid economic growth and increasing demand for better healthcare, China has become one of the most important emerging markets for AstraZeneca. We fully support China's national focus on innovation by substantially increasing our R&D investment, both in financial terms and in terms of scientific collaboration. In addition, AstraZeneca has recently announced its plans to establish the Innovation Centre China. The Centre will focus on translational science by developing knowledge about Chinese patients, biomarkers and genetics. The initial therapeutic area for the Innovation Centre will be cancer, which is a major cause of death in China. Furthermore AstraZeneca will expand its clinical research capabilities and is looking this year to increase the number of scientific collaborations with local Chinese organizations. To further demonstrate its commitment to being "In China, For China", AstraZeneca is partnering with government organizations and industry associations to develop academic and management knowledge among medical professionals and hospital executives. AstraZeneca has also initiated a number of programs on disease education and public health. At the same time, AstraZeneca is committed to being a good corporate citizen by fulfilling important social responsibilities. AstraZeneca has a strong commitment to core values that are founded on good business practices and compliance. AstraZeneca supports the government in striving for integrity in the healthcare system

Sanjay Batra, Vice President, R&D Pharmaceuticals, Johnson & Johnson

Enhancing Global Drug Development Through the Formation of Loose Networks: In this presentation Dr. Batra will share his view of the importance of developing loose networks to achieve break-through results in a global environment. In an era of incredible technological advancement, 'Geography' is becoming 'History' and access to subjects, patients, customers is closer than ever before. The formation of loose networks don't just happen and Dr. Batra will address how one might develop a carefully constructed plan to take ideas and turn them into new opportunities through the formation of loose networks.

1:00-4:40 **Session 2:** (英文)***Current Trend in Global Pre-Clinical and Clinical Research, Development, and Collaboration***

Mark Engel, President and CEO, Excel PharmaStudies, Inc.

Clinical Trials in China: Drivers and Opportunities

- 6 key Drivers for Rapid Growth in Numbers of Trials Coming to China
- How Our Client Companies Taking Advantage of this Growth Trend
- Examples of Some Hidden Gems: Unusual and Unique Opportunities Presented by the China Clinical Trial Environment

临床研究在中国：动因和机遇

- 进入中国的临床研究数量快速增长的 6 个关键动因。
- 我们的客户怎样把握这一增长趋势。
- 独具慧眼：中国临床研究环境所提供的与众不同和独特的机遇。

Dr. James Cai, VP of R&D, China, AstraZeneca Pharmaceutical Co., Ltd

Opportunities and challenges to a multinational pharmaceutical company in China: This presentation is to address the opportunities and challenges we are facing in China as a multinational pharmaceutical company, and how competition in China is extending from the fields of sales, marketing & manufacturing to R&D.
The fast expansion of China's economy creates opportunities of pharmaceutical market, which is unprecedented in industry history. In terms of R&D, China's government support for innovation is leading to stronger IP protection enforcement, and is paving the way for regulatory dialogue on early phase clinical research.
Most important of the challenge is the huge unmet medical need in China, especially in the Oncology and CV area besides anti-infection. R&D can contribute to tackle these challenges, through making sure Chinese patients benefiting from innovative medicine with appropriate price / or market access

Le Sun, Ph.D., President and CEO, Welson Pharmaceuticals, Inc.

Immunoconjugates for cancer therapy: The therapeutic activity of "naked" anti-EGFR antibodies is very modest and Erbitux was approved only for use in combination with chemotherapy by FDA. It is highly desirable to generate so called "Immunoconjugates" by arming the tumor-specific mAbs with cytotoxic drugs to enhance their anti-cancer activity. Welson has developed several anti-EGFR mAb LA22-immunoconjugates by arming tit with several anti-tumor antibiotics, including Mitomycin (MMC). We have shown 1) in *in vitro* cytotoxicity assays MMC alone or LA22-MMC prodrug kill cancer cell lines more efficiently than the same dose of naked mAb LA22; 2) LA22-MMC prodrug is much potent in the treatment of subcutaneous xenografts of human A431 cells in nude mice. The specific immunoconjugate was significantly more effective than free drug MMC or naked LA22 antibody; 3) Most importantly, LA22-MMC is much more potent cancer cell killer than Erbitux, Herceptin, Erbitux-MMC or Herceptin-MMC.

Xiao Chang Dai（戴晓畅）, Ph.D., General Manager, Sino-American Kunming Baker Norton Pharmaceutical Co.,

Chinese Generic Pharmaceutical Sector, Evolving under the New Selection Pressure: Dr. Xiao Chang Dai received his Ph.D. from Dr. Jerry Joyce's lab, The Scripps Research Institute and his Post Doc. Training form Dr. John Abelson's lab, Caltech. After retruning to China, he has been holding the positions of Chairman, Unida Co., LTD, and CEO, Da Lian Hisenn Biopharmaceutical Co., LTD prior to his current role in Kunming Baker Norton Pharmaceutical Co., LTD
This presentation will share a very personal view about Chinese generic pharmaceutical industry with strong emphasis on reimbursement policy, tendering, price setting mechanism and their impact on the Chinese pharmaceutical marketing and sales

Zili Li, M.D., Director, Clinical Operation, Asia Pacific, Merck & Co., Inc.

Chinese SFDA vs. US FDA - regulatory challenges and realities in globalization of medicine development. Based on the predictions from The Boston Consulting Group (BCG), China, by 2010, will probably have leapfrogged major European markets to become world's fifth-largest national market for pharmaceuticals, with sales likely to reach $25 billion. That is why many multi-national pharmaceutical companies (MPCs) are intensifying their marketing and R&D efforts within China. Those efforts, however, face many regulatory challenges that may delay the approval of clinical trials or the marketing of drug product in China.
This presentation compares Chinese regulatory system with that of US FDA and calls for the needs to first understand the Chinese regulatory system and take the interests of China into the consideration (not only that of MPCs) in promoting the regulatory reform and alignment with international standard and practice in China.

Samantha Du, Ph.D., Managing Director, Hutchison Medipharma Ltd., Chief Scientific Officer & Executive Vice President, Hutchison China Meditech Ltd.
Dr. Du joined Hutchison in June 2001 as Senior Vice President and has led all aspects of development and management of the company's R&D strategy. In 2002, she gained HWL's approval for the establishment of Hutchison MediPharma and has built up the company to over 70 employees. Dr. Du has led the advancement of two Phase II US clinical trials; the establishment of a rich discovery portfolio in less than three years; and establishment of strategic alliances with world leading research institutions and companies. Dr. Du is a well-recognized leader in the R&D arena in China through her advisory roles to various government bodies. Dr. Du started her research career at Pfizer's Global R&D site in Connecticut and led teams that delivered multiple INDs and NDAs for various anti-infective, cardiovascular, and metabolic medicines. Dr. Du's last role at Pfizer was in the Global Strategic Operations Group where she was in charge of licensing and related M&A activities in the metabolic disease area.

Nathan Zhang, Chairman and CEO, Laviana Corporation

Innovation, capitalization and entreupeurship of the chinese life science industry. Dr. Nathan Xin Zhang is the Chairman and CEO of Sinocro Inc（Laviana Inc）, one of the largest Chinese companies providing chemistry outsourcing services for global pharmaceutical and biotech companies. Before founding Sinocro Partners, Dr. Zhang was the CEO of Chipscreen Bioscience; Dr. Zhang build Chipscreen into the largest R&D based Biotech Company focused on discovery of novel small molecule drugs. Chipscreen was recognized as one of the ten most potential biotech and pharmaceutical company at the 2002 Asia Pacific Life Science and Pharmaceutical summit. Chipscreen was awarded seven national "863" projects and two Guangdong government most significant achievement project grants. Chipscreen raised 6M USD venture fund in 2001 from Venture investors. China Medicine Economic News recognized Dr. Zhang as one of "China's New Strength, Top Individuals of China Pharmaceutical Industry" in 2003. Prior to joining Chipscreen, Dr. Zhang was the Managing Director at Delirium, a global strategic consulting company in New York. Dr. Zhang was a senior consultant at KPMG LLP's New York office before Delirium. Prior to joining KPMG, Dr.Zhang worked at the Credit Suisse First Boston's investment banking group in New York. Dr. Zhang was a scientific co-founder of CDR Therapeutics, Inc., a Seattle-based bio-pharmaceutical startup. Dr. Zhang received his Ph.D. in pharmacology from the Medical School of University of Pennsylvania, M.D. from Tianjin Medical University's Eight Year Program, and MBA from the University of Chicago with a concentration in Finance and Accounting. Dr. Zhang was awarded James A. McLaughlin Award from American National Student Research Forum and Brupbacher Young Investigator Award from Charles Rudolph Brupbacher Foundation in Switzerland. Dr. Zhang is an active promoter of Chinese Pharmaceutical and biotech industry on global forums and among global industry leaders. Dr. Zhang was invited speaker at Harvard China Review 2004 Conference, Wharton China Business Forum 2004, Sachs Bloomberg Global Biotech and Pharmaceutical Investment Forum in Boston, Bio2004, and IBC conference series... on the topic of current and future development of Chinese biotech and pharmaceutical industry. Dr. Zhang is currently on the board of director of Venture Pharm, a Hong Kong listed Chinese research and pharmaceutical company. Dr. Zhang is also on the advisory board of Hainan State government, Beijing Pharmaceutical Group, Xian Bu Chang Pharmaceuticals, Guang Zhou Consun pharmaceutical company etc.

Lingwen Zeng, Ph. D. Investigator， Head of Laboratory of Molecular Diagnostics, Guangzhou Institute of Biomedicine and Health (GIBH), Chinese Academy of Sciences

Capitalizing on China based R&D: Capitalizing on China based R&D. With a booming economy and increasing affluent population, China's pharmaceutical market has expanded dramatically in the past twenty years and is projected to become the fifth-largest by 2010. Multinational pharmaceutical companies have increasing interest in this growing market and are exploring to launch R&D operations in China. However, most of these activities are limited in scale and have yet to become fully integrated R&D. As the Chinese government attempts to attract investments and technologies that can help China to make a transition from "manufacturer of the world" to "R&D of the world", developing R&D capability has become a critical path for the future success of the industry. Chinese companies should eventually play a major role in R&D, but academia is currently the driving force for discovery research in China. Industry and academia must truly work together in order to capture the value. R&D models that can maximize utilization of resources will be able to capitalize on China-based R&D and to build a complete value chain that ranges from discovery to market China.

William Goebel Vice President, CimQuest

1:00-4:40 **Session 3:** (中文)***Current Advances in Drug Discovery, Research, Development, and Regulation in China***

Mr. Weidong Yin, Chairman & CEO, Sinovac Biotech Ltd.

The Role of Chinese Owned Biotech Company In Global R&D Partnership. This presentation will discuss about the general situation of Chinese biotech companies. The discussion will help US and Western companies and organizations to make strategic consideration in finding the suitable partners in China. Using the success experience of Sinovac, the presentation will elaborate on why partner with a Chinese company, and what to look for in a partner Chinese biotech company. Specifically, Sinovac's achievements in international collaboration, vaccine innovation and product development will be reviewed.

Jason Jin, Ph.D. President of MaxyBio Corporation, USA,
Senior VP, Global Business Development, ShanghaiBio (Shanghai Biochip) China

Outsourcing with China in Drug Discovery and Development through Systems Biology. We have established a multidisciplinary capability to provide whole solutions of systems biology using multiple biochip platforms of DNA/protein/tissue/SNP arrays, and post-array validation technologies. Combining experimental and bioinformatics techniques, we are able to provide the high quality services or global collaborations from biochips towards drug targets using approaches of genomics, proteomics and pharmacogenomics. Our platforms for systems biology have already demonstrated a potential broad impact on projects at all stages of drug discovery, preclinical researches, and clinical studies. This talk will illustrate our technologies for systems biology solutions and how they could support the discovery and development of new medicines.

Guozhong Rui (芮国忠), *Director*, China Pharmaceutical Technology Transfer Center, SFDA, China.

Pharmaceutical R&D in China： The Marketing Opportunities and Business Model: The global market of pharmaceutical R&D outsourcing is increasing rapidly, the author analyze deeply the drive factors, fields inner and extension which is enlarging continuously for the pharmaceutical R&D outsourcing , especially describe in detail the characteristics of chain and market scale of pharmaceutical R&D industry in China; Comparatively analyzing the R&D outsourcing strategies and business models for new drug development between multinational pharmaceutical companies and local Chinese companies, indicate the key and successful factors to improve the new drug development and innovation ability; Finally through analysis of the strength, weakness ,opportunity and threat (SWOT), the author emphasizes that the local Chinese pharmaceutical companies must to participate in the global cavalcade of new drug development , and suggest that we first become a global "R&D outsourcing" and " technology application" distributing center , then to a "technology increase" base , ultimately turn into the" technology innovation " country for novel drug development in the world.

Zegong Zhang（张泽工），北京生物技术和新医药产业促进中心副主任，中关村生物工程和新医药企业协会秘书长、北京生物工程学会理事、注册咨询师. 张泽工先后参与和承担国家生物技术产业规划研究、北京市“十五”生物医药规划、北京生物医药产业报告、中关村生物工程和新医药产业报告、生物新医药产业链等研究及撰写工作。先后参与国家北方生物医药基地中试基地、国家人类基因组北方研究中心等重大项目的组织实施。参与中关村生命科学园、北京经济技术开发区（“药谷”）.北京生物工程与医药产业基地等项目规划设计。先后组建并负责北京生物医药种子项目投资联盟、中关村生物工程和新医药企业协会、中国生物技术研发联盟、同仁堂发展委员会等工作。张泽工负责生物中心咨询业务，先后接受企业委托咨询项目近20项，涉及企业战略、市场调研、投资可行性分析等。张泽工主任1999年为北京科技咨询业协会授予注册咨询师资格。1997年开始组织北京生物医药产业发展论坛，成功举行九届，在海内外具有广泛影响。长期从事医药行业分析、政策研究、项目组织实施及风险管理；重大活动的组织实施等工作，具有丰富经验与医药相关管理机构、研究开发机构、投资公司、企业、咨询机构保持长期合作的关系。

Qiang Zhang, Ph.D., Professor; Vice President, School of Pharmaceutical Sciences, Peking University

Advances of Drug Delivery Systems in China. As an important embranchment of pharmacy, pharmaceutics has contributed a lot to the pharmaceutical sciences and pharmaceutical industry in China in many ways. The main researching fields of drug delivery systems (DDS) in China include targeted drug delivery system, sustained and controlled drug delivery system, transdermal drug delivery system, drug delivery system for macromolecules, and so on. With the fast development in sciences and technology, the researches on new pharmaceutical materials, new technology, new methods and even basic researches have entered a new phase. All these evolution bring impacts on the pharmaceutical industry in China. In this review, the course of development of DDS in China has been reviewed, hot point in researches of DDS has been analyzed, the achievement has been introduced and finally the trend has been expected.

Honggang Bi, Ph.D. CEO, Frontage Laboratories, Inc, China

Global Pharmaceutical R&D, How Do We Win the Game with Chinese Contract Research Organizations? This presentation will take a look at the current trend of pharmaceutical R&D outsourcing In China. Case studies will be used to show the advantages and challenges about outsourcing drug discovery and development activities to China for US pharmaceutical companies.

Wenseng Pan, J.D. & Ph.D., Morgan Lewis & Bockius

Licensing and Collaborations in Drug Research, Development and Commercialization In China - Opportunities and Pitfalls. Drug research, development and commercialization is a long and risky road, each stage has its challenges and will take years of hard work and efforts. At the same time, each stage presents its unique licensing and partnership opportunities to Chinese pharmaceutical and biotech companies. Licensing-in a promising drug candidate can significantly reduce the time and risks of the drug discovery process, which has paramount importance in today's competitive world. Forming a strategic partnership with a major player in the industry could help an emerging company both technically and financially. However, companies should be aware of the pitfalls in exploring the opportunities.This presentation will discuss how to protect a party in a license or collaboration transaction by using different license options, alternative financial arrangements, a governing body, preserving IP ownership and allocating risks, etc.

Gangqiang Cai, Director of GZ Municipal, Science & Technology Bureau

Guangzhou and Bio-medical Industry: Dr. Cai Gangqiang, the Director of Science & Technology Bureau of Guangzhou Municipality, received his Master and Ph.D. degrees in Automation from South China University of Technology, in 1987, and 1993, respectively. After graduation, he worked as teacher at Central South China University of Forestry & Technology; Division Chief of High and new technology department of Guangzhou Science & Technology Bureau; and Vice Director of Guangzhou S&T Bureau. He served as the Director of Guangzhou S&T Bureau since 2003.

4:10-5:40 **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 international market place in the next one & two decades?

Panel Modulator:

Ling Chen, M.D., Ph.D., Director-General, Guangzhou Institute of Biomedicine and Health (GIBH),,Chinese Academy of Sciences CAS. Dr. Ling Chen is the founding Director General of the newly established GIBH (www.gibh.ac.cn). Prior to returning to China in 2004 to build this institute from scratch, Dr. Chen has been residing in the USA for 19 years in academia and industry. From 2001-2003, Dr. Chen was the founding Director of Biotherapeutics at Lexicon Genetics Inc., where he directed discovery of novel therapeutic proteins and antibodies. From 1997-2001, he was a Senior Research Fellow at Merck Research Laboratories, Merck & Co. where he worked on drug and vaccine R&D for HIV, HPV, influenza, and cancer and was the first inventor of a Merck's novel HIV vaccine that is in clinical trial. Prior to joining Merck, he was an Instructor at Harvard Medical School where he pioneered several approaches for cancer treatment. His inventions in HIV vaccine and cancer chemotherapy are now in human clinical trials. Dr. Chen received his medical training from the Shanghai Medical College from 1979-1984. He was a CUSBEA fellow of 1984 and obtained a Ph.D. in Biochemistry and Molecular Biology from Indiana University and had postdoctoral training at Dana-Farber Cancer Institute, Harvard Medical School.

Panel Modulator:

Ling Su, Ph.D., Director， Medical and International Pharma Development , Shanghai Roche Pharmaceutical Ltd.

Dr. Ling Su is currently responsible for all clinical studies and medical marketing in Shanghai Roche Pharmaceuticals Ltd. and also serves as Medical Director for Roche Hong Kong. His professional career includes working in the Chinese drug regulatory agency in late 1980s and in the US FDA in early 1990s. He joined Merck Research Laboratories (MRL) in 1996 as an Epidemiologist, was the Medical Director for Merck Sharp & Dohme (China) in 2000-2002 and was Senior Director, Global Strategic Regulatory Development in MRL in 2003. He joined Shanghai Roche in Dec. 2003 to lead global clinical development operations in China and Hong Kong. He received his BS degree in clinical pharmacology from Shanghai Medical University, China; and MS degree in drug development and PhD in epidemiology, both from the University of North Carolina at Chapel Hill, USA. His professional and research interests encompass the fields of regulatory affairs, clinical research, pharmacovigilance, risk management and outcomes research. He has been actively involved in the advancement of regulatory affairs and clinical research in the Asia Pacific region and particularly in China. He has been a member of the Drug Information Association (DIA) since 1995 and has organized five DIA conferences in China in the past six years. He was a member of SAPA Executive Council in 1999-2001 and in 2003'

Panelists
All afternoon speakers joined by Ruyi He, Manager, FDA, USA and Mark Tang, CEO, World Technology Ventures, etc.

6:00-9:00 **Session 5:** (中文) ***Banquet: Pearl River Night Banquet*** **(珠江之夜晚宴招待会)**

Lin Yuanhe, Executive Vice Major, Deputy secretary general of Guangzhou City

Guangzhou's Development Strategy and entrepreneurial Environment: Mr. Lin Yuanhe is Executive Vice Mayor of Guangzhou City and Deputy Secretary of the Guangzhou CPC Committee. He was born in 1950 in Fujian province. He joined the workforce in January 1969 and become a member of the CPC in December 1981. He holds a Master degree of management (Faculty of Management Science and Engineering, Chinese Scientific and Technical University) and is qualified as engineer.

Liu Yuelun, Vice Chairman of Guangzhou Development District(GDD)

Highlights of Guangzhou Development District and its bio-medical industry: Dr. Liu Yuelun is Deputy Chairman of the Administrative Committee of the Guangzhou Development District. He graduated from the University of Liverpool with a Ph.D. degree in Public and Business Administration. After returning from the UK in 1993, he joined Hong Kong Effectual Holding Co. Ltd. Later, he initiated the Guangzhou Convention of Overseas Chinese Scholars in Science and Technology and has been the founding Chairman of Guangzhou Entrepark. He has been elected to be the Chairman of the Oversea Guangdong PhDs Entrepreneur Association.

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Asia Pacific Network (APN), West Point Chapter, Merck

Pre-Conference Workshop:

FDA Filing and GMP Compliance

June 16, 2006 1:00 pm -6:30 pm (中文版请看下一页)

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640 W. Germantown Pike, Plymouth Meeting, Pennsylvania 19462-1003, USA
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Chair: Lee Kang, PhD, MBA, **Sanofi-Aventis**

Main Theme:

- Understand filing requirements in general for API and drug products, and specifically for API supplying for generic drug manufacturers.
- Understand FDA regulations and filing requirements for various types of submissions (DMF, IND, NDA, and ANDA), and familiar with the mechanism and requirements for reporting post-approval changes.
- Learn how to build regulatory affairs personnel in dealing with FDA and North American clients and learn how to develop strategy for filing CMC information to FDA.
- Learn strategies on how to get regulatory agency and American clients' inspection of your facilities.
- Meeting GMP Requirements and Customers' Expectations in order to Seize Outsourcing Opportunities.

FDA Organization and Medical Review Divisions
(**Ruyi He**, MD, PhD, **FDA**)

- FDA organization and division responsibilities
- Filing and communication channels with FDA
- New initiatives and recent changes in FDA

Regulatory Affairs' Roles in Pharmaceutical Companies and in Dealing with FDA
(**Jiwen Zhang**, PhD, **Wyeth**)

- Cultural differences between industry and FDA
- Effective and constructive interactions
- Manage communication strategies

DMF Submission Mechanisms and Overview
(**Jane Xiang**, PhD, **Johnson and Johnson**)

- DMF types and submission mechanisms
- Relationship of DMF with other regulatory submissions
- DMF holder's responsibilities and how to handle process changes

CMC Information Requirement and Strategy
(**Naidong Ye**, PhD, **Vela Pharmaceuticals**)

- IND submissions and data requirements
- NDA and ANDA submissions
- Risk based design and question based review

Pre-Approval Inspection and Post Approval Changes and Comparability Protocols
(**Lee Kang**, PhD, MBA, **Sanofi-Aventis**)

- Understand FDA's system-based inspections and meet ICH Q7A expectations
- Understand BACPAC and SUPAC for post approval changes
- Report mechanisms Comparability protocol development

Panel Discussion and Q/A

会前学习研讨班主题：FDA Filing and GMP Compliance

“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，及 GMP 认证”

1. 会前研讨班 2006 年六月 16 日 1:00-6:30 PM
2. 课程将以中文讲授
3. Moderator: **Lee Kang, PhD, MBA (Sanofi-Aventis)**

培训课题大概内容 (deliverables):

1. 了解美国食品药品监管局对原料药和仿制药制剂的法规要求，以及 GMP 认证开始
2. 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
3. 美国食品药品监管局对新药研发监控管理法规以及在公司研发和生产中的功效和影响
4. 新药临床申请(IND)申报前、临床试验中以及新药申请(NDA)申报前和美国食品药品监管局的交流讨论会
5. 准备美方(FDA or Partner)对(中国)企业在申报前及合同签署前的 GMP 检查

时间　　课题　　(讲授员)

1:00 主讲致辞，简介讲员

1:30-2:15 美国食品药品监管局 FDA 组织机构和职责划分 (Ruyi He, MD, PhD, FDA)
- 美国食品药品监管局 FDA 的主要任务和文件审查部门
- 药品申报及审批的一般程序以及和 FDA 联络的方式
- 美国食品药品监管局 FDA 最近动态和机构的改组

2:15-3:00 接触 FDA 官员的最佳人员队伍监控管理法规组 Regulatory Affairs 的任务和使命 (Jiwen Zhang, PhD, Wyeth)
- 美国政府和民营企业的文化区别和意识差异
- Regulatory Affairs 主要负责的项目
- 与 FDA 联络的方式、策略和实战技巧

3:00-3:45 美国食品药品监管局 FDA 对药物主文件 DMF 的要求和审查程序 (Jane Xiang, PhD, Johnson & Johnson)
- 药物主文件 DMF 的种类和审请审查程序以及提交的 CMC 数据资料要求
- DMF 和其它申请报批文件（NDA, ANDA, MAA 等）之间的关系
- 药物主文件 DMF 持有者的责任以及如何申报核准后工艺的变更

3:45-4:30 美国食品药品监管局 FDA 对化学制造及控制（CMC）数据资料的要求及相应的送审策略 (Naidong Ye, PhD, Vela Pharmaceuticals)
- 新药临床研究申请报批文件（IND）的要求
- 新药申请审核批准报批文件（NDA）的要求
- 新药申请 NDA 和简略新药申请（即仿制药申请）ANDA 的 CMC 数据资料要求

4:30-5:15 FDA 对新药申请批准前工厂现场检查（PAI）以及批准后工艺变更和申报的要求 (Lee Kang, PhD, MBA, Sanofi-Aventis)
- 了解 FDA 以系统为基准的工厂现场检查
- FDA 核准后的后续事项和相应的补充文件(合成工艺批准后变更 BACPAC 和制剂批准后变更 SUPAC)
- 如何利用相类似变更协定 comparability protocol 来处理核准后工艺的变更 post-approval change

5:15-6:00 互动交流及问答

6:30 课程总结

Post-Conference workshop:

Modern Process of Drug Development Workshop: from Discovery to Commercialization

June 18, 2006 9:00 am - 5:30 pm (中文版请看下一页)

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	8:30 am	Registration
		Morning Session Chair: Hua Marlon Zhong (Johnson & Johnson)
	8:55 am	Opening Remark
		Drug Discovery
Drug Discovery Research	9:00 am	Introduction to basic research in drug development Chang Bai, Research Fellow, Molecular Endocrinology/Basic Research Merck
Medicinal Chemistry	9:30 am	The role of medicinal chemistry in drug discovery Wenyong Wang, Principal Scientist, Medicinal Chemistry GSK
	10:00 am	Morning Tea Break
		Chem & Pharm Development
Process Research & Development, and GMP	10:30 am	Chemical Process Research & Development: Roles and Challenges Hua Marlon Zhong, Principal Scientist, Group Leader, Chemical Process R&D, Johnson & Johnson
Pharmaceutical Sciences	11:00 am	Introduction to Pharmaceutical Preformulation Lian-Feng Huang, Associate Director, Pharmaceutical Development, Johnson & Johnson
Analytical Development and GLP	11:30 pm	Analytical Development – The Key to Control Product Quality Chan Ko, Research Fellow, Analytical Development, Johnson & Johnson
	12:00 pm	Lunch Break
		Afternoon Session Chair: Chang Bai (Merck)
		Pre-clinical Development
Toxicology and drug safety	1:30 pm	Role of preclinical safety assessment in drug discovery and development Yun Zhang, Sr. Research Toxicologist, Safety Assessment, Merck
Drug Metabolism (PK/PD)	2:00 pm	The role of Drug Metabolism in preclinical drug discovery and development Chunze Li, Research Fellow, Drug Metabolism, Merck
Formulation	2:30 pm	Overview of Pharmaceutical Solid Dosage Formulations and Processes Wayne Wang, Principal Scientist, Pharmaceutical Development, Johnson & Johnson
	3:00 pm	Afternoon Tea Break
		Clinical Development and Commercialization
Clinical Research	3:30 pm	Overview of Clinical Trials in a Typical New Drug Development Program Tsang-Bin Tzeng, Sr. Director, Clinical Pharmacology, AstraZeneca
	4:00 pm	Execution of Clinical Trials in the US and Europe Maggie Zhang, Sr. Scientist, Trial Design, Centocor, Johnson & Johnson
Marketing	4:30pm	Providing Commercial Leadership to Drug Development Kai Li, Manager, Global Biologics Strategic Marketing, Johnson & Johnson
	5:00 pm	Closing Remark

会后学习研讨班主题

“当代国际医药研究，开发，制剂，质量控制，临床研究，生产,及上市的全过程”

2006 年 6 月 18 日 9 am – 5:30 pm：Chair: Hua Zhong (Ph.D. J&J) and Chang Bai (Ph.D. Merck)

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。为了向 SAPA 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）

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

新药的化学和药物开发

- 药物化学生产流程的研发，作用和挑战
- 临床前期药物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
- 分析化学：药物生产流程研发过程中质量控制的关键

临床研究前开发

- 药物安全性评估在新药研发中的作用
- 临床前药物的吸收分布代谢关键研发
- 临床药物的固态剂型设计和流程优化

新药申报 (will be covered by June 16 workshop)

- 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

临床研究和新药上市

- 新药研发中的临床研究综述
- 在美国和欧洲执行临床研究
- 新药行销的策略和实践对新药研发的指导作用