



Sino-American Pharmaceutical Professionals Association
-Greater Philadelphia Chapter
美中医药开发协会大费城分会

Monte Jade Science and Technology Association
Mid-Atlantic Chapter
美中玉山科技协会



SAPA-GP & Monte Jade Joint Annual Conference 2009

*First Ever Conference Jointly Held by Two Premier Professional Organizations in the Greater Philadelphia Area
You Are Invited to Be Part of This Historic Event*

Innovation Partnership Globalization Present Challenges and Strategies for Biotechnology and Pharmaceutical Industry



Keynote Speakers

Dr. Shiew-Mei Huang

Deputy Director, Office of Clinical Pharmacology
Center for Drug Evaluation and Research (CDER), FDA
President, American Society for Clinical
Pharmacology and Therapeutics

Mr. Rich Fante

President, AstraZeneca US

Mr. Mark Larsen

President, Asia Pacific and Global Nutrition
Wyeth

Dr. Chi-Huey Wong

President, Academia Sinica, Taiwan

Dr. Li Chen

Chief Scientific Officer, Roche China

Friday & Saturday, May 15 -16, 2009

**The Learning Center, Temple University Ambler Campus
580 Meetinghouse Road, Ambler, Pennsylvania**

For Program Details & To Register Online: www.sapa-gp.org

Organizing Co-Chairs

Li Yan, MD, PhD
President, SAPA-GP
Vice President, SAPA

Tsang-Bin Tzeng, PhD
President-Elect, SAPA-GP
Chairman of Monte Jade

The Joint Annual Conference of SAPA-GP and Monte Jade is a two-day event, featuring chief executives from biotechnology and pharmaceutical companies, who will discuss:

- Current challenges in our industry & The impact of mergers & acquisitions
- Innovative strategies to thrive in the current crisis & Opportunities and challenges in the \$34.2 billion biologics industry

Career Forum & Job Fairs: New opportunities in external research, outsourcing, and virtual R&D

Conference Partners



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Conference Contact Information

Li Yan, Li_Yan@merck.com; Tsang-Bin Tzeng, Tsang-Bin.Tzeng@astrazeneca.com

Please contact sapa@sapa.com for exhibition, hiring needs, or to become a conference partner and sponsor

Conference Agenda

Friday, May 15, 2009

8:00 - 8:45 AM

Registration

8:45 AM - 12:00 PM

Session I:

Present Challenges and Strategies for the Biotechnology and Pharmaceutical Industry

Moderator: Li Yan, MD, PhD (SAPG-GP President 2008-2009)

Senior executives from major pharmaceutical companies and pharmaceutical and biotechnology organizations will discuss present challenges facing the biotechnology and pharmaceutical industry. The speaker will present their thoughts on innovation, partnership and globalization to address the issues of rising R&D costs, declining productivity, surging patent expirations and revenue shortfalls in order to survive and thrive in the current economic crisis.

- Mergers & Acquisitions: Sizes, but not only Sizes Matter
- Emerging Market: Innovative R&D and Sustainable Market in Asia Pacific
- Expediting Pharmaceutical R&D through Biomarker Initiative
- Biotechnology and Pharmaceutical Industry in Pennsylvania, New Jersey and Delaware

8:45 - 9:00 AM

Welcome & Opening Remarks

Li Yan, MD, PhD

SAPA-GP President

Keynote Speakers

9:00 - 9:40 AM

Personalized Medicine- Challenges and Opportunities in Drug Development, Regulatory Review and Clinical Practice

Shiew-Mei Huang, PhD

Deputy Director, Office of Clinical Pharmacology, Center for Drug Evaluation and Research (CDER), FDA
President, American Society for Clinical Pharmacology and Therapeutics

9:40 - 10:20 AM

Winning the Right Way in Today's (US) Pharmaceutical Market

Mr. Rich Fante

President, AstraZeneca US

10: 20 - 10:35 AM

Break

10:35 - 11:05 AM

Mergers Don't Work....So Why Do We Do Them?

Mr. Frank LaSaracina

Principal, SouthPoint Associates LLC

11:05 - 11:35 AM

Biosimilars: Sense and Non-Sense

Geert Cauwenbergh, Dr. Med. Sci.

Chairman, BIO NJ; CEO & Chairman, RHEI Pharmaceuticals

11:35 - 11:55 AM

Special Addresses

Mr. Dennis M. "Mickey" Flynn, President of Pennsylvania BIO

Dr. Geert Cauwenbergh, Chairman of BIO NJ

Mr. Bob Dayton, President of Delaware BIO

11:55 AM - 12:00 PM

SAPA-GP Election Results Announcement

12:00 - 1:00 PM

Lunch (Complimentary to All Registered Attendees)

1:00 – 3:55 PM

Session II:

Biologics - Opportunities and Challenges of the \$34.2 Billion Industry

Moderators: Peter Luo, PhD and Laura Hong, MD, PhD

Expert speakers from some of the major players in biologics industry will discuss opportunities and challenges in the \$34.2 billion biologics market. Experts in healthcare economics and policy will examine the impact of the Obama administration's new healthcare policies on the pharmaceutical industry, especially the proposal to speed the availability of generic versions of biologic drugs or "biosimilars". Regulatory experts will analyze FDA and EMEA requirements in developing novel biologics and biosimilars.

- Biopharmaceutical Industry – Strategy & Vision
- Healthcare Reform and its Impact on Biologics
- R&D of "Biosimilar" and "Bio-Better" Biologics
- Clinical Development & Regulatory Considerations
- Manufacturing & Commercialization

Featured Speakers

1:00 - 1:35 PM

Preventing HPV-Related Epithelial Cancers by Vaccination

Eliav Barr, MD

Vice President, Oncology Clinical Research – Scientific Operations at Merck Research Laboratories
2009 PhRMA Discoverers Award Recipient -for his contribution in the development of Gardasil™

1:35 - 2:10 PM

The Development of Follow-on Biologics: A Perspective Based on Actual Experience

Hillel Cohen, PhD

Head, Regulatory Affairs for the Americas & Head, Regulatory Affairs for Early Development
Novartis Vaccines & Diagnostics, Inc.

2:10 - 2:45 PM

Challenges and Opportunities for the Biopharmaceutical Industry

David Robinson, PhD

Vice President, Bioprocess, Merck & Co., Inc.

2:45 - 3:20 PM

Accelerated Growth Markets - Wyeth Approach to Maximizing Potentials in Emerging Markets

Mr. Mark Larsen

President, Asia Pacific and Global Nutrition, Wyeth Pharmaceuticals

3:20 - 3:55 PM

Immunoprophylaxis of RSV Infection: Advancing from RSV IGIV to Palivizumab and Motavizumab

Herren Wu, PhD

Vice President, Global Head of Technology and Lead Generation, Head of Antibody Discovery & Protein Engineering, MedImmune

3:55 - 4:10 PM

Break

4:10 – 6:00 PM

Session III:

Career Forum & Job Fairs

Moderators: Jingsong Wang, MD and Joshua Zhang, MD, PhD

Keynote Speakers

4:10 - 4:40 PM

Endless Career Opportunities in the Pharmaceutical Sciences

Karen Habucky, PhD

Executive Director, Drug Regulatory Affairs, Novartis Pharmaceuticals Corporation

2008 President of the American Association of Pharmaceutical Scientists (AAPS)

4:40 - 5:10 PM

The Opportunities and Challenges for Top Talent in Asia

Martin Reynolds

Chief Executive Officer, Sharpstream Life Sciences

The demand for top talent in Asia is high, and will continue to increase, as more organizations enter developing markets and transfer research, development, and manufacturing capacity to the region. Considering this demand and indeed the almost “gold rush” mentality that exists for hiring organizations and talent, this session will provide insight on key areas where the requirement for experienced talent is desired. It will provide insight and recommendations on what is critical for organizations and what should be critical for talented executives that are considering a move or return to the region. Finally recommendations on what make a good leader and how executives should audit themselves to ensure that they “market” and represent themselves to their full potential.

5:10-6:00 PM

Job Fair and Networking

Selected hiring companies/agency will have representatives on site to meet with candidates
Position profiles are listed in the conference program



Integrated Drug Discovery



Food and Drug Administration



Sino-American Pharmaceutical Professionals Association
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美中医药开发协会大费城分会

Monte Jade Science and Technology Association
Mid-Atlantic Chapter
美中玉山科技协会



Friday, May 15, 2009

7:00 – 10:00 PM

Dinner Reception

Organizers: Weihong Hsing, PhD, JD & Wensheng Lang, PhD

Lai Lai Garden

1144 Dekalb Pike, Blue Bell, PA 19422 Phone: (610) 277-5988
www.lailai garden.com [Get directions](#)

SAPA-GP Award Ceremony

To celebrate the achievements of SAPA-GP
To acknowledge the contributions of dedicated individual members
To appreciate the strong support of partners and friends

Featured Speaker

Alan E. Kligerman

Founder and CEO of AkPharma

How to Succeed in Business by Really Trying



Mr. Kligerman has created many innovative products such as Lactaid[®], Bean[®], Prelief[®], CatSip[®] and CurTail[®]. He will tell the story of how a business that started by delivering ice cream morphed into serious food technology and then into skin treatment and wound care. He will also share a baker's dozen of do's and don'ts on how to become an entrepreneur.

Special Performance by Violinist

Johnna Wu



A freshman at Columbia University, Johnna began studying violin with her grandfather at the age of four. She made her debut performing in the annual Yuletide Celebration of Indianapolis with the Indianapolis Symphony Orchestra at the age of eight. Since then, she has won numerous competitions and soloed with Carmel, New World, Indianapolis, Pottstown, and Delaware Symphony Orchestras. She has recently had the honor of performing in Carnegie Hall in New York.

Enthusiastic in community service, Johnna will perform for the second time at the SAPA annual conference. She will play both traditional Chinese and classical western music.

Saturday, May 16, 2009

8:30 AM – 12:10 PM

Session III:

Global Innovation and Partnership

Moderator: Tsang-Bin Tzeng, PhD (SAPA-GP President-Elect)

Key opinion leaders from both governmental and industrial sectors will present their strategies and initiatives in establishing world class biotechnology and pharmaceutical R&D hubs in Asia Pacific. They will share their visions in promoting the region as a new center of innovative drug discovery and in transforming the emerging market into a major market. Learn from these experts how to leverage these new opportunities and enter into these new areas to sustain growth

- China Biotechnology and Pharmaceutical Industry Strategy & Vision
- Translation of Early-stage Discoveries into Commercial Opportunities
- Asia Pacific: the New Innovation Center for Global Pharmaceutical R&D

Keynote Speakers

8:30 – 9:05 AM

Translation of Early-stage Discoveries into Commercial Opportunities

Dr. Chi-Huey Wong (翁启惠)

President, Academia Sinica

9:05 – 9:40 AM

A New Way of Doing Drug Discovery: Approach from East

Dr. Li Chen (陈力)

Chief Scientific Officer, Roche China

9:40 – 10:15 AM

Chinese Healthcare System Reformation

Mr. Ming-De Yu (于明德)

Executive Vice Chairman, China Pharmaceutical Enterprise and Management Association & China Pharmaceutical Entrepreneurs Association

10:00 – 10:15 AM

Break

10:15 – 10:45 AM

Virtual Proof of Concept (VPOC) in Drug Discovery

Allen I Oliff, MD

Senior Vice President, GSK

10:45 – 11:15 AM

Contour™ In Silico Structure Based Drug Design and Optimization of Novel Orally Active Renin Inhibitors

David A. Claremon, PhD

Vice President of Chemistry, Vitae Pharmaceuticals

11:15 – 11:45 AM

Mergers, Acquisitions and Other Vehicles in a Dynamic Environment

Augustine Yee, JD

Senior Director, Astra Zeneca

11:45 – 12:10 PM

Recent Developments in the Dynamic Landscape of Drug Discovery and Development in China: Capitalizing on Integrated Services for Enhancing Productivity

Rich Soll, PhD

VP of Medicinal Chemistry, WuXi Apptech

12:10 – 1:10 PM

Lunch (Complimentary to All Registered Attendees)

1:10 – 5:40 PM

Session IV:

Innovative R&D Models

Moderator: Chris Pak, PhD

What innovative R&D models can be leveraged to address rising R&D costs, declining productivity and surging patent expirations? Speakers from pharmaceutical, biotechnology and CRO companies will discuss the following:

- Virtual R&D Centers
- External Research / Outsourcing
 - Target Biology
 - Innovative Drug Discovery, e.g., structure-based approaches
 - Preclinical Drug Evaluation
 - Biomarkers & Translational Sciences
 - Clinical Development & Regulatory Matters
- Mergers, Acquisitions and Other Vehicles in a Dynamic Environment
- Impact of Outsourcing on Your Job Role and Security, and New Opportunities
- Intellectual Property Protection and Patent Issues in Collaborative R&D

Featured Speakers

1:10 – 1:35 PM

Key Elements in Translating Ideas into Viable Businesses in Life Sciences

Darren Ji, MD, PhD

Board of Directors, BayHelix; President & CEO, PharmaLegacy

1:35 – 2:00 PM

World Financial Crisis: Positive or Negative for China Drug Development

Mark Engel

CEO, Excel Pharma Studies

2:00 – 2:25 PM

Boost the Capacity of Innovation by Integrating with China Biology CRO

Larry Wang, PhD

President, GenScript Corporation

2:25 – 2:45 PM

CRO for Drug R&D Externalization: Challenge and Opportunity

Boliang Lou, PhD

CEO, Pharmaron

2:45 – 3:05 PM

Perspective on Integrated Drug Discovery Service in China – Opportunities and Challenges

Han-Cheng Zhang, PhD

VP of Medicinal Chemistry, ChemPartner

3:05 – 3:20 PM

Break

3:20 – 3:40 PM

Drug Development during Financial Crisis: Innovative Global Approach

Dan Zhang, MD, PhD

Board of Directors, BayHelix; President and CEO, Fountain Medicine

3:40 – 3:55 PM

Product Advancement in Molecular Imaging and Cancer Therapeutic

Chris Pak, PhD

President and CEO, Molecular Targeting Technologies

3:55 – 4:10 PM

Frontage, Your Partner in Pharmaceutical Product Development

Song Li, PhD

CEO and Chairman, Frontage Laboratories

4:10 – 4:25 PM

New Business Models to Help Fund Discovery Research

John Oyler, PhD

President & CEO, BioDuro

4:25 – 4:40 PM

An Integrated Nanotechnology-based CRO for Biological Drug Development

Ray Yin, PhD

President & CEO, ANP Technologies, Inc.

4:40 – 4:55 PM

Partnering in Translational and Biomarker Assays at China

Jason Jin, MD, PhD

President & CEO, ShanghaiBio

4:55 – 5:05 PM

Fully Integrated Affordable Research Service will be the Future

Bill Guo, PhD

Chairman & Founder, Venturepharm Group

5:05 – 5:15 PM

Julius Li, PhD

CEO, AutekBio, Inc.

5:15 – 5:25 PM

R&D Partnership and Licensing: An Efficient Development Model for Chinese Pharmaceutical Industry

Allan Riting Liu, MD, PhD, MBA

Vice President, Wanbang Biopharm Co. Ltd

Chief Director, Business Development of the Group, Fosun Pharmaceutical Group

5:25 – 5:40 PM

Conclusion and Discussion

5:40 PM Adjournment

Speakers' Bio's

Listed alphabetically based on the last name



Eliav Barr, MD

Vice President, Oncology Clinical Research – Scientific Operations at Merck Research Laboratories

Dr. Eliav Barr is Vice President, Oncology Clinical Research – Scientific Operations at Merck Research Laboratories in West Point, PA USA. In this role, he is responsible for clinical trials planning and execution in the area of oncology, one of Merck's fastest growing areas of research.

Dr. Barr joined Merck & Co., Inc. in 1995 and in 1998 became the head of the Human Papilloma Virus (HPV) vaccine clinical program. He developed the clinical/regulatory strategy for the program; designed and managed 17 clinical studies involving over 30,000 subjects worldwide; developed a program to evaluate the economic impact and long-term efficacy of the HPV vaccine, and oversaw analyses of key clinical studies. The program resulted in the first demonstration of prophylactic efficacy for a vaccine targeting HPV (Koutsky et al. N Engl J Med 2002;347:1645-51), and the first demonstration that prophylactic administration of a vaccine targeting HPV types 6, 11, 16, and 18 is highly effective in reducing cervical, vulvar, and vaginal cancer risk and genital wart rates caused by these types (FUTURE II Study Group. Lancet 2007; 369:1861-1868; FUTURE I Study Group. Lancet 2007;369:1693-1702). The vaccine that was evaluated in these studies (GARDASIL[®], Merck & Co., Inc.) has been licensed in over 100 countries. Over 25,000,000 doses have been distributed.

Dr. Barr received his medical degree from the Jefferson Medical College in 1986 (summa cum laude) and completed an Internal Medicine residency, a Cardiology Fellowship, at Johns Hopkins in 1990. He subsequently pursued post-doctoral training at the University of Michigan, and was on faculty at the University of Chicago prior to joining Merck.



Geert Cauwenbergh, Dr. Med. Sc.

CEO & Chairman – RHEI Pharmaceuticals

Founder & CEO – Phases123 LLC.

Founder – Barrier Therapeutics Inc. (NASDAQ: BTRX)

In August 2008, Dr Geert Cauwenbergh was named CEO and Chairman of RHEI Pharmaceuticals, a company that in-licenses western pharmaceutical products for the Chinese and SE Asian markets, takes these products through the regulatory channels, and provides the commercial support for successful launch, marketing and distribution of these products through its own organization and through strategic regional partnerships.

In February 2008, Geert founded Phases123, a company focused on high potential health care technology platforms and emerging health care companies. Phases123 provides the necessary support structure around these platforms and companies, creating accelerated growth, by building management teams, facilitating product and business development and providing access to capital and geographical expansion.

Prior to founding Phases123, Dr. Cauwenbergh founded Barrier Therapeutics in September of 2001; a biopharmaceutical company with focus on research and development of patented drugs for treatment of skin diseases. He raised private financing for the company in May of 2002 and took the Company public with a listing on the NASDAQ (Symbol: BTRX) in April of 2004. Through capital raises for a total of \$250 million, he developed Barrier Therapeutics from a pure R&D organization into a commercial US company with 3 products in the market and \$45 million in revenues in 2008, as well as a broad and deep pipeline of innovative treatments in development. Barrier Therapeutics was acquired by Stiefel Laboratories in August of 2008.

Prior to founding Barrier Therapeutics, Dr. Cauwenbergh was Vice President of Technology of the Johnson & Johnson (J&J) Consumer and Personal Care Products Companies. In this capacity, he created technology platforms based on intellectual property and know-how owned by Johnson & Johnson, and developed business plans around these platforms as the basis for new companies or new businesses within J&J.

Previously, Geert served as global Vice President of R&D of the J&J Consumer Companies Worldwide, and he was a member of the J&J Business Development Council. In 1994, Dr. Cauwenbergh moved from Europe to the USA, and became Vice President of Product Development and member of the Board of the US Johnson & Johnson Consumer Company. He also served as Director of the J&J Skin Care Council, coordinating all skin care activities in the different operating groups of the Corporation.

Geert joined the R&D organization of the Janssen Research Foundation in Belgium in 1982. He held positions of increasing responsibility and oversaw development of drugs such as Sporanox[®], Nizoral[®] Shampoo, Terazol[®], and topical Sufrexa[®]. His R&D activities have involved him in the fields of psoriasis, acne, wound healing, atopic dermatitis, protozoal infections, and HIV. Early in his career, starting in 1979, in Janssen

Pharmaceutica in Belgium, he worked in sales, national and international marketing, and he was responsible for the successful global introduction of Nizoral® (ketoconazole).

Between 2003 and 2005, Dr. Cauwenbergh served on the Board of Directors of Intercept Inc, a small privately held biotechnology firm with focus on liver diseases. He is a member of the Board of Trustees, and current Chairman of Bio New Jersey . Between 2004 and 2006 he served as a member on the Board of Trustees of the New Jersey Center of Life Sciences. In 2004, Dr Cauwenbergh was appointed Official Trade Advisor for Health Care in North America to the Belgian Government, a function which was renewed in 2007. In 2007, Geert was named on the Board of Ablynx NV and Euroscreen SA, 2 biotechnology companies in Europe. He joined the Board of Upstream Biosciences, a small biotechnology company in Vancouver, Canada, as well as that of a privately held biotech company, ECI Biotech, in Massachusetts, USA

Dr. Cauwenbergh has authored over 100 publications and co-authored several books. He received his Ph.D. in Medical Sciences from the Catholic University of Leuven, Faculty of Medicine, where he also completed his Masters and undergraduate work.

In 2004 Dr. Cauwenbergh was inducted in the New Jersey High Tech Hall of Fame.



Li Chen, PhD
Chief Scientific Officer, Roche China

Li Chen, Ph.D., is the Chief Scientific Officer at Roche's R&D Center in Shanghai, reporting to Dr. Lee Babiss, President and Global Head of Roche Pharma Research. He is a member of Roche Pharma Research Leadership Team and Board of Directors of Roche R&D Center China. In 2004, he was one of the pioneers helping to build up the center in a record seven months. Besides developing and implementing the Research strategy for China as well as handling external collaborations and research programs, he remains a scientist at heart. With a current team of 90 scientists, he drives Discovery Research mainly in medicinal chemistry and research technology. He also manages the Research operations including chemistry, pharmacology, biology and discovery technology, as well as Research informatics and inventory in Shanghai. Li has been with Roche since 1992. He started out as a Senior and Principle Scientist in drug discovery research in Nutley. His co-invention of R411, a clinical drug for asthma, dates back to these years. While in Nutley, he also assumed the role as Head of Combinatorial Chemistry and established the respective department with a focus on high quality lead generation. Before going back to China to take his current position, Li led the High Throughput Chemistry and Research Project from 2000 to 2004. He also served as a member of the Roche Patent Coordination Committee in Nutley – quite appropriate given that he has more than 50 patent applications and scientific publications of his own.

Li holds a bachelor's degree in 1982 from Zhengzhou University in China. He continued his academic career earning a master's degree in 1985 from East China Normal University in Shanghai where he also gave lectures in Organic and Synthetic Organic Chemistry. Li, a Chinese citizen, completed his university education with a Ph.D. in Organic Chemistry from Iowa State University in the United States in 1992.



David A. Claremon, PhD
Vice President of Chemistry, Vitae Pharmaceuticals

After receiving a Ph.D. in Organic Chemistry under the direction of Professor K.C. Nicolaou at University of Pennsylvania, Dr. Claremon began a career of over 25 years in medicinal chemistry at Merck Research laboratories. While at Merck, his research group successfully identified several development candidates including an anti-arrhythmic (MK-499) and an oral fibrinogen receptor antagonist (L-738,167). David joined Vitae Pharmaceuticals in 2002 to enable and advance the discovery of novel molecules using computational structure based design. This effort created an approach which has enabled Vitae to successfully identify orally active renin inhibitors, 11-beta HSD inhibitors and beta Secretase inhibitors. He has authored over 60 publications and is an inventor on 80 patents.



Hillel Cohen, PhD
Head, Regulatory Affairs for the Americas & Head, Regulatory Affairs for Early Development
Novartis Vaccines & Diagnostics, Inc.

Dr. Hillel Cohen is Head of Regulatory Affairs for the Americas and for Early Development in Novartis Vaccines and Diagnostics. He has 19 years of experience in Regulatory Affairs, in positions of increasing responsibility. Regulatory issues that he has addressed include pre-clinical, clinical, analytical, and manufacturing topics related to both biologics and biotechnology products. Dr. Cohen is chair of the Vaccine

Committee of the Pharmaceutical Research and Manufacturers Association. In addition to his leadership roles in vaccine regulatory affairs, Dr. Cohen has also been an active participant in developing science-based policy related to follow-on biologics (biosimilars) in the US.



Mr. Mark Engel
Chairman, Excel PharmaStudies, Haoyisheng, Tiger Medical Group

Mark is the co-founder of Excel PharmaStudies, the largest full service clinical research organization in China with operations in Beijing, Shanghai, Guangzhou, Chengdu, Chongqing, Nanjing, Xian, Wuhan, Dalian, Hangzhou, Changsha, Taizhou, Tianjin and Shenyang (and increasingly operations throughout Asia, including a regional headquarters in Singapore). In the last several years, Excel has been involved in about 185 phase I to IV trials in 30 cities at about 160 hospitals, and covering around 165,000 patients. The trials have been for either purposes of local registrations or for international approvals. Our clients include most of the top 20 international pharmaceutical companies and many of the leading Chinese pharmaceutical companies.

Mark is also the co-founder of several other medically related companies in China: (1) **Haoyisheng**, the leading health care information, education and database management company in China with about 500 employees; and (2) **Tiger Medical Group**, including Tiger Medical Products, Tiger Health Care Group, and Tiger Medical Sourcing.

Mark lives in Shanghai with his wife and two sons. In his spare time Mark likes to play bad golf.



Mr. Rich Fante
President, Astra Zeneca US

As US President of AstraZeneca, Rich Fante directs AstraZeneca's largest market - the United States. AstraZeneca is one of the world's leading pharmaceutical companies. Rich is accountable for driving US growth and maximizing contribution to AstraZeneca's global business.

Previously, Rich served as Vice President, Brand Strategy & Portfolio Operations, leading the development and execution of marketing strategies for all AstraZeneca brands in the United States. He has held a number of leadership roles in his 13 years at AstraZeneca, including Vice President-Primary Care for the gastrointestinal and respiratory franchises, including NEXIUM® (esomeprazole magnesium) and PULMICORT RESPULES® (budesonide inhalation suspension). Before joining Astra USA in 1995, Rich worked for Lederle Laboratories in New Jersey, where he began his career in sales.

Rich received his Bachelor's degree in biology from Princeton University and Master of business administration, University of North Carolina Kenan-Flagler Business School.



Bill Guo, PhD
Chairman & Founder, Venturepharm Group

Dr. Bill Guo is the Chairman and founder of Venturepharm Group, a leading full service plus pharmaceutical company in Asia, and led its two flag ship Venturepharm lab to become the first CRO company listed in HK and CBI group, the first Chinese company made acquisition in NSDAQ. he has spent over 9 years global pharmaceutical experiences from researcher to senior executive e.g. Johnson & Johnson, Novapharm and Venturpharm Canada in North American. 9 years of entrepreneurs experiences in China.

After obtained the medical degree in China, Bill went to Canada to pursue his Master and Ph.D Studies with respectively, pharmacokinetics and physical pharmaceuticals from the University of Toronto, MBA programs from Herriot Watt University and Executive education from Judge Business School, University of Cambridge UK

Fortune magazine recognized him as one of the most potential entrepreneurs in China. He was also recipient of various rewards: 2005 National Hero awarded by the state council of China; One of the Ten best management elites in China in 2004, one of the ten most influential individual in economic field of China, 2005. Distinguished entrepreneur awarded from oversea by government of China, 2005. Sole winner of

Youth Chinese Entrepreneur Award organized by Asia Business Week in 2003. 2005 Entrepreneurs and innovation by BCC (British Chamber of Commerce);



Karen Habucky, PhD

**Director in Drug Regulatory Affairs, Novartis Pharmaceuticals Corporation
2008 President of the American Association of Pharmaceutical Scientists (AAPS)**

Karen Habucky, Ph.D. was the 2008 President of the American Association of Pharmaceutical Scientists (AAPS) and has been an active volunteer in Association for more than 15 years. She also held the position of Member-at-Large on the AAPS Executive Council. Other AAPS volunteer activities include Chair of the Program Coordination Committee (2002), Annual Meeting Programming Committee (2001), Training Task Force (2003) and Task Force Chair for the Section Strategic Visioning (2004). Karen currently mentors several junior scientists and graduate students, is actively involved in Visiting Scientist Program, and visited 3 Schools of Pharmacy this year. Karen has a passion for teaching and served as a PERI faculty member where she taught several pharmacokinetic and drug development courses for many years.

Dr. Habucky received a B.S. in pharmacy and a Ph.D. in pharmaceutical sciences with an emphasis in pharmacokinetics from the University of Pittsburgh under the guidance of Dr. Raman Venkataraman.

Currently, Karen is a Executive Director in Drug Regulatory Affairs at Novartis Pharmaceuticals Corporation in the immunology and infectious diseases. During her career, she had held various leadership positions in regulatory affairs, preclinical pharmacokinetics, drug metabolism, clinical pharmacokinetics and toxicology. She has held positions at various pharmaceutical firms such as Johnson & Johnson, Sandoz Research Institute and Huntingdon Life Sciences.



Shiew-Mei Huang, PhD

**President (2009-2010) of the American Society for Clinical Pharmacology and Therapeutics
Deputy Director, Office of Clinical Pharmacology, Center for Drug Evaluation and Research (CDER), FDA**

Dr. Huang is currently Deputy Director, Office of Clinical Pharmacology, Center for Drug Evaluation and Research (CDER), FDA. She received her B.S. in Pharmacy from National Taiwan University, School of Pharmacy and her Ph.D. from University of Illinois, Medical Center in Pharmacokinetics and Biopharmaceutics. She has 15+ year drug development experience (Ortho pharmaceutical Corp. and Dupont-Merck Pharmaceutical Company) before joining the FDA in 1996. She chairs CDER working groups that prepared a guidance on drug interactions and a concept paper on pharmacokinetics in renal impairment. She is a member of the FDA Interdisciplinary Pharmacogenomics Review Group and an alternate member of the FDA Drug Safety Oversight Board.

She has published over 100 peer-reviewed articles and book chapters focusing on topics in clinical pharmacology, drug metabolism/interactions and pharmacogenomics areas and has been invited to present more than 60 presentations in the past 5 years (2003-2008) at national and international meetings and workshops. Dr. Huang is on the editorial boards of several journals including Clinical Pharmacology and Therapeutics, Expert Review in Clinical Pharmacology, Biomarkers in Medicine, , Journal of Clinical Pharmacology, Expert Opinion- Pharmacotherapy; Pharmacogenomics. She has received many awards, including the FDA Outstanding Achievement Award, FDA Clear Communication Award, and FDA Distinguished Service Award. Dr. Huang is an AAPS Fellow (American Association of Pharmaceutical Scientists) and a diplomate of the American Board of Clinical Pharmacology. She is the President (2009-2010) of the American Society for Clinical Pharmacology and Therapeutics.

Dr. Huang served as Chair, Chinese American Community Center, Hockessin, DE in 1994-1996, President, American Chinese Pharmaceutical Association in 2000, and President, Chinese-American Professionals Association- Metropolitan Washington DC in 2001. In addition, she is an avid Toastmasters International member since 1997.



Darren Ji, MD, PhD, MBA

CEO and Co-Founder, PharmaLegacy Laboratories

Dr. Darren Ji is the CEO of PharmaLegacy Laboratories, a Shanghai-Zhangjiang based CRO Company focusing on providing preclinical specialty pharmacology services (www.pharmalegacy.com).

Previously, Dr. Ji was the Director of Bioscience Business Development –East Asia for the Procter & Gamble Company where his overall responsibility was identifying and bringing business opportunities in bioscience-related fields from Greater China, Japan and South Korea to P&G. Dr. Ji successfully engineered a number of significant transactions between P&G and bioscience entities in the East Asia region. Two of the deals were cited by Yahoo Finance as being two outstanding activities of P&G in external alliances in 2007. Dr. Ji maintains an extensive business network in the bioscience community around the world, in particular in the US and Asia.

During his extensive career at P&G, Dr. Ji had extensive experience in drug research and management and initiated and managed multiple research and development drug projects, both internally and through external partnerships, with biotech companies and research institutions in the US, Europe and Asia.

As a frequent invited speaker and panelist at major biotech and pharmaceutical meetings, Dr. Ji speaks on topics of international business development in life sciences. He obtained his MD in Clinical Medicine at China Medical University, China; PhD in Biotechnology at the University of Sheffield, UK; and MBA in Entrepreneurship and Organizational Management at the University of Chicago Graduate School of Business, USA.

Dr. Ji's has been recognized and honored by various organizations including the BayHelix Group (www.bayhelix.org) where he serves on the Board Directors, the International Chinese Hard Tissue Society (www.ichtso.org) (USA) where he served as President and continues as an active member of the Board of Directors, and Nankai University and Chinese Academy of Sciences where he holds a Guest Professorship.



Mr. Alan E. Kligerman
Founder and CEO of AkPharma

Mr. Kligerman is an entrepreneur who has created many innovative products such as Lactaid[®], Beano[®], Prelief[®], CatSip[®] and CurTail[®]. AkPharma is dedicated to the idea of creating products to help you comfortably maintain your health by letting you eat a wider variety of healthful foods.

Alan E. Kligerman is the founder and Chief Executive Officer of AkPharma Inc. He is also the founder and was Chief Executive Officer of Lactaid Inc., which introduced and marketed lactase enzymes to the U.S., Canadian and worldwide markets. Born in Atlantic City, New Jersey, Alan Kligerman attended schools in Margate and Atlantic City, New Jersey. He studied dairy industry at Cornell University, making him the third generation of his family in the dairy business. The family firm, Kligerman Dairies, operated in Atlantic City from 1919 to 1965.

In 1962 Mr. Kligerman founded SugarLo Company which produced and marketed low-sugar frozen desserts and other food products. In 1974 Mr. Kligerman started the business that evolved into Lactaid Inc., which marketed over-the-counter lactase enzyme tablets and dairy-produced lactose-hydrolyzed milk for persons who are lactose intolerant. In 1990 and 1996, Mr. Kligerman licensed, and then sold, the Lactaid brand to McNeil Consumer Products Division of Johnson & Johnson. In every year since 2001, Lactaid Milk has been the largest selling branded milk in the United States.

In 1991 Mr. Kligerman founded AkPharma Inc., to market his invention, the oral use of alpha galactosidase enzyme to make beans, legumes, and a wide variety of similar vegetables more digestible. He obtained U.S. and worldwide patents on these uses, and he created the brand name Beano[®] for it. The Beano brand and patent rights were sold to Block Drug Company, Inc., now part of Glaxo SmithKline, in 1997.

Mr. Kligerman has been on the Government Affairs and Public Relations Committees of the Dairy & Food Industry Supply Association. He has also been Treasurer and Board member and has served on various committees of the Calorie Control Council. He has twice appeared before the House Judiciary Subcommittee of the U.S. Congress on food industry matters and has testified before the House on behalf of the U.S. Department of Agriculture. During the Special Food and Drug Hearings in the early 1970s he was one of the founders of the U.S. Council on Special Foods, created to defend the use of sorbitol as a food ingredient.

He was a member of the Advisory Council of Cornell University's Institute of Food Science, 1990-1996. In 1995 he was appointed by President Clinton to the Board for International Food and Agricultural Development, a unit of the U.S. Agency for International Development.

In 1987, Mr. Kligerman/Lactaid Inc. shared the Institute of Food Technologists (IFT) Industrial Achievement Award, the highest food technology award in the U.S. given in industry.



Jason (Gang) Jin, MD, PhD
President & CEO of ShanghaiBio Corporation

Dr. Jason (Gang) Jin is the President & CEO of ShanghaiBio Corporation (SBC for CRO), and Co-Founder & Executive VP of Global Business of Shanghai Biochip Co. Ltd (SBC), a leading biotech in China with lab operations at Shanghai and global business office at New Jersey in U.S. Dr. Jin is also an adjunct professor at the Shanghai Institutes of Biological Sciences (SIBS), Chinese Academy of Sciences (CAS). Dr. Jin has extensive scientific and business development experience in drug discovery and development. He has successfully developed and managed a number of R&D collaborative projects in biology discovery, preclinical research, and clinical trials with top global pharmaceutical and biotech companies. Dr. Jin has held the former positions of Director of Genomics Lab at Purdue Pharma (USA), Director of Functional Genomics at Salk Institute (USA), Founder Director of National Engineering Center for Biochip at Shanghai (China), and radiologist at Shanghai Zhongshan Hospital (China). He received Ph.D. and Postdoctoral Fellow in biology from University of California, San Diego (USA), and medical degree from School of Medicine, Fudan University (Shanghai Medical University, China).



Mr. Mark Larsen
President, Asia Pacific and Global Nutrition, Wyeth Pharmaceuticals

Mr. Larsen was named President, Asia/Pacific and Global Nutritionals Business Unit for Wyeth Pharmaceuticals in June 2005. He had served as President - Europe/Middle East/Africa of Wyeth Pharmaceuticals from July 2002 to June 2005, and President of the Intercontinental Region (Asia-Pacific/Latin America) for Wyeth Pharmaceuticals from March 1998 to July 2002.

Mr. Larsen joined the Corporation in 1994 as a result of the acquisition of American Cyanamid Company as a Group Vice President, Asia. Subsequently, he was made Group Vice President, Asia-Pacific in 1996. Mr. Larsen was appointed to the Operations Committee of the Corporation in January 2001.

Prior to joining the Corporation, Mr. Larsen was employed by SmithKline Beecham where he worked in both the consumer and ethical divisions and was based for five years in New Zealand and Japan. He then joined Bristol-Myers Squibb Company and spent additional time in Japan as well as in the U.S. Marketing Group and the International Business Development Group. Mr. Larsen joined American Cyanamid Company in 1994 as Vice President of Asia-Pacific for Lederle International.

Mr. Larsen has served as the Chairman of the Pharmaceutical Research and Manufacturers of America (PhRMA) Asia-Pacific Committee, on the Asia Pacific Board of Directors of Project Hope, on the Board of Directors of Princeton-In-Asia and is currently Chairman of the PhRMA Japan Committee. Mr. Larsen is a graduate of Princeton University.



Mr. Frank LaSaracina
Principal, SouthPoint Associates LLC

Frank LaSaracina is founder of SouthPoint Associates LLC, a consultancy focused on bio-pharma companies. With over 30 years of relevant business experience and nearly 25 years in bio-pharma, Mr. LaSaracina assists clients with their business development, expansion, and financing needs.

Prior to founding SouthPoint Associates LLC, Mr. LaSaracina was Managing Director of Speedel Pharmaceuticals, Inc, the US subsidiary of Speedel Holding, the Basel based bio-pharma company that was acquired by Novartis at a value of approximately CHF 1.0 billion in October of 2008.

Mr. LaSaracina has extensive international experience in business development and licensing, strategic planning, and corporate development in the pharmaceutical industry. During his twenty years with Ciba/Novartis he held numerous management positions, first as director of finance in the US and then in various business development positions. In addition, Frank has led complex global project teams in areas of strategic planning, business restructuring and mergers and acquisitions. Prior to joining Speedel in 2000 as Managing Director of Speedel Pharmaceuticals, Inc., he was vice-president with responsibility for marketing, program management, information technology and strategic management while at Hurley Consulting, a contract research organization. Frank, a CPA, started his career within the Advisory Services Group at Deloitte and Touche, providing services to clients in the retail, manufacturing and services sectors.

Frank is past trustee of the Oradell Board of Education as well as Newark Beth Israel Hospital, and from 2004 through 2008 served as Treasurer of the Biotechnology Council of New Jersey.



Allan Riting Liu, MD, PhD, MBA
VP, Wanbang Biopharm Co. Ltd
Chief Director, Business Development Department, Shanghai Fosun Pharmaceutical Group

Dr. Allan Riting Liu is in charge of the business development of Fosun Pharma Group and the new drug development of Wanbang Biopharma, a subsidiary of Fosun, developing R&D strategies and exploring the global opportunities via in-licensing, equity investment as well as M&A. Prior to Fosun, he worked as Business Development Director for Venturepharm Group in Beijing and also as General Manager of Venturepharm Asia in Malaysia, and was a scientist at Eli Lilly U.S. headquarter in developing osteoporosis and cancer drugs. He began his career in sales/marketing at Xian-Janssen and then worked as Manager of Marketing at Guangdong Institute of Med. Devices. He received an MBA at Purdue University, a Ph.D. in biochemistry at University of Texas /M.D. Anderson Cancer Center, and an M.D. from Guangzhou Medical College.

Dr. Liu's recent achievements including two technology transfers to Alpharma (U.S.), creation of the BD Department of Fosun Pharma Group, establishment of a joint-venture company with Anesiva (U.S.) for manufacturing needle-free lidocaine injection for the global market, and setting up a new drug R&D company for Fosun with some U.S. scientists. He has evaluated hundreds of development products/target companies world-wide in the fields of diabetes, cardiovascular diseases and tumors, and has established global network with numerous pharmaceutical companies or institutions. In 2003, he received an honor/award as Guidant Scholar offered by Guidant Foundation (U.S.). In 2008, he received an honor as One-Million-Yuan-Subsidized Top Talent offered by Jiangsu Government (China).



Boliang Lou, PhD
Chairman and Chief Executive Officer, Pharmaron, Inc.

Dr. Boliang Lou co-founded Pharmaron in 2003, and is a recipient of the Beijing Overseas Returnee Entrepreneur Award in 2008.

Dr. Lou previously served as the Director of Research at Advanced SynTech (AST), managed a multi-discipline team working in the area of drug discovery, combinatorial, high throughput medicinal and computational chemistry. At AST, he was responsible for all the collaboration projects with various pharmaceutical, biotech companies and academic institutions around the world.

He received his M. S. degree (1986) and Ph.D. in organic chemistry (1989) under the supervision of Professor Li-Xin Dai at the Shanghai Institute of Organic Chemistry (SIOC). He did post-doctoral research with Professor Stephen Hanessian at the University of Montreal (1990-1994). Dr. Lou then joined Cytel Corporation in San Diego, California in 1994. He began working on combinatorial chemistry after joining Ontogen Corporation in 1996. One year later, he moved to Helios Pharmaceuticals (later as Advanced SynTech) as Staff Researcher II and became the Research Section Head of Chemistry in 1998 and the Director of Research in 2002.



Allen Oliff, MD
SVP Molecular Discovery Research, GlaxoSmithKline Pharmaceuticals

Dr. Oliff graduated *cum laude* from Brandeis University in 1971 and attended the Albert Einstein College of Medicine in New York City until 1974. Thereafter, he completed his training in Internal Medicine at the Bronx Municipal Hospital Center in New York, and obtained fellowship training in Medical Oncology in the Clinical Oncology Program of the National Cancer Institute at the National Institutes of Health in Bethesda, Maryland. Upon completion of his clinical training, Dr. Oliff entered the laboratory of Dr. Edward Scolnick as a post-doctoral fellow from 1978 to 1981 where he was trained in molecular genetics and tumor virology. In 1981, Dr. Oliff accepted his first independent research position as an Assistant Member of the Memorial Sloan Kettering Cancer Center in the department of Molecular Biology and Virology. Four years later Dr. Oliff was promoted to an Associate Member of the Memorial Sloan Kettering Cancer Center and was also appointed as an Associate Professor in the Cornell University Graduate School of Medical Sciences - Sloan Kettering Division. In 1985 Dr. Oliff was recruited to the Merck Research Laboratories in Pennsylvania as the Director and head of Cancer Research. In 1991 he was appointed to the position of Executive Director of Cancer Research at Merck and Co.

During his career at the N.I.H., Memorial Sloan Kettering, and Merck, Dr. Oliff pursued investigations into the molecular pathogenesis of cancer. These studies focused on RNA tumor viruses, oncogenes, and tumor suppressor genes. Dr. Oliff has authored over 120 peer reviewed publications in these fields, and has been an invited speaker at numerous national and international meetings on these topics. In addition to being a Board Certified Internist and Medical Oncologist, Dr. Oliff is a member of the American Society of Clinical Investigation, the Harvey Society, the American Association for Cancer Research, the American Society of Hematology, the American Society of Clinical Pharmacology and Therapeutics, and the American Society of Clinical Oncology. He has received the Louise and Allston Boyer Award for Cancer Research from the Memorial Sloan Kettering Cancer Center, and a Scholar Award from the Leukemia Society of America. Dr. Oliff has served as a member of the Board of Scientific Counselors of the National Cancer Institute and is an Adjunct Professor of Pharmacology at the Thomas Jefferson University College of Medicine. He also serves on the editorial boards of "Cancer Research" and "Cancer Metastasis Reviews", "Current Medicinal Chemistry - Anti-Cancer Agents", "Molecular Cancer Therapeutics", and is a past consulting editor for "CANCERGRAM: Antitumor and Antiviral Agents".

Dr. Oliff has developed several anticancer agents and brought three of these agents into clinical trials including recombinant fusion proteins targeting the EGF-receptor, farnesyl transferase inhibitors, and a selective drug delivery system targeted against prostate cancers.

Dr. Oliff joined DuPont Pharmaceuticals in April of 1999 as Vice President of Biology Discovery Research with responsibilities for the Departments of Anti-Viral Research, Cancer Research, and Applied Biotechnology. He was subsequently promoted to Senior Vice President of Drug Discovery with the added responsibilities of Anti-microbial Research, Medical Imaging, and Radiotherapeutics.

In May of 2001, Dr. Oliff joined GlaxoSmithKline as Senior Vice President and Head of the Center of Excellence for Drug Discovery (CEDD) in charge of Cardiovascular, Oncology, and Genitourinary diseases. Later that year, Dr. Oliff moved to the newly created CEDD in charge of Oncology, MusculoSkeletal, Antimicrobial, Dermatology, and parasitic diseases in Upper Providence, Pennsylvania and became site director for that facility. In July of 2006, Dr. Oliff was appointed Head of the newly created Molecular Discovery Research department at GSK, and joined the Research and Development Executive (RADEX) team reporting to the head of R&D, Moncef Slaoui.



John V. Oyler
Chief Executive Officer, Bioduro, Beijing Co. Ltd

John is a serial entrepreneur with a track record of success who has started and managed 8 companies and has raised over \$225 million in capital.

During his career, Mr. Oyler has been responsible for a wide array of activities including: raising partnering with multi-national companies, instigating clinical trials at Sloan Kettering, Sidney Kimmel, and Mass General, licensing and managing intellectual property, building software-database-statistical capabilities to handle extremely large-scale data, and most importantly building highly functional, world-class organizations.

In the biotech field John been started (or re-started, in the case of Genta) 4 companies.

Galenea (private). Most recently, John helped Susumu Tonegawa (Nobel laureate; Howard Hughes Investigator; MIT) and Jianzhu Chen (Professor in the Cancer Research Center at MIT) acting as CEO during its first two years. Galenea is a drug discovery company in Cambridge, MA developing drugs for CNS disease (schizophrenia) and respiratory disease (siRNA-based). Galenea partnered with Otsuka Pharmaceuticals and has \$50 million in capital.

Genta (Nasdaq - GNTA). John served as co-CEO of this publicly company in 1998 when it had failed and was valued at \$US5 million. John helped raise additional capital, restarted 7 clinical programs, and hired a new management team. These programs proved successful and Genta has since had a market capitalization of over \$US1.6 billion.

Walden Laboratories (merged into Indevus -IDEV). John helped start this CNS company (serotonin activator), acting as VP of Operations. Walden Labs was merged into Interneuron Pharmaceuticals (now Indevus) in 1994. Subsequently, the combined company reached a market capitalization of \$US1.8 billion.

Oasis Biosciences (sold to Genprobe -GPRO). John helped start this nucleic acids company which was sold to GenProbe (Nasdaq, market capitalization of Genprobe of \$US2.4 billion).

Outside of the biotech field John has been involved in starting 4 companies:

Telephia (private, profitable, growing). John Founded and co-managed this outsourced services company for the telecommunications industry. Telephia has raised over \$US120 million in capital, is profitable, and growing at nearly 20% per year. Telephia has extensive capabilities in software development, extremely large-scale data management, and statistical analysis and quality control.

Verdisoft (sold with extremely attractive returns). John helped start this company and served as a general manager for its first year. Verdisoft is a cutting-edge software company that was sold to Yahoo and is at the center of many of their recent product offering initiatives.

RTI. John helped found and manage, RTI, a coatings company that develops coatings similar to Gortex. RTI partnered with the textile conglomerate Formosa and was eventually sold to a competitor.

In addition, Mr. Oyler was involved for several years in performance improvement and strategic growth initiatives at McKinsey & Co., the international consulting firm where he spent 1992-3 working in China.

Mr. Oyler holds a BS in Engineering from The Massachusetts Institute of Technology and a MBA from Stanford Business School.



Chris Pak, PhD
President & CEO, Molecular Targeting Technologies, Inc.

Dr. Chris Pak is a co-founder, President and CEO of Molecular Targeting Technologies, Inc. (MTTI), a U.S. based Biotechnology Company focused on developing novel imaging products as well as potent vaccines. He was previously employed by Centocor, a top-tier Biopharmaceutical company, where he focused on the research and development of novel products for unmet medical needs. He is the co-founder and former Chairman of the Chinese Entrepreneur Association and the former Vice Chairman of the Global Monte Jade Science and Technology Association, organizations responsible for promoting entrepreneurship. Dr. Pak currently holds 10 patents in diagnostic imaging and therapy and has published over 50 articles relating to the use of antibodies for cancer and cardiovascular disease. He was recently awarded by the State University of N.Y. for the Honor Roll of Alumni, the Ben Franklin for the Emerging Business Award and the Asian Chamber of Commerce for the Outstanding Asian American Business Award.



Mr. Martin Reynolds
CEO, Sharpstream Life Sciences

Martin Reynolds has over 20 years of consulting experience working the life sciences industry. Between 1989 and 1999, Martin worked at IMS Health, a global provider of business intelligence and consulting services, holding roles in Data Management, Quality, New Product Development, Marketing and Commercial. As the Vice President for New Business Development, he was instrumental in establishing a group that was responsible for the on-boarding of five major new companies in a two year period. In 1999, Martin moved to Datamonitor Plc, global business intelligence provider where he was responsible for Healthcare Sales and Marketing. He was instrumental in the re-engineering of the business from a report based service provider to a consulting services provider.

In 1999, Martin was responsible for the establishment of Sharpstream Life Sciences, a global retained search firm, which currently has offices in London, Philadelphia, and Shanghai. Martin serves as the CEO and the Managing Director for North America. The organization is comprised of over 45 executives that are responsible for the execution and delivery of more than 150 retained searches completed across the global and increasingly in Emerging Markets. The organization is specialized only in Life Sciences with its capabilities ranging from discovery through to commercialization. As the demand for true global search work increased, particularly in Asia where major talent pools are based in North America, Sharpstream Life Sciences has developed innovative research and consulting methodologies in order to successfully drive repatriation of top talent into the Asia.



David Robinson, PhD
Vice President, Bioprocess, Merck & Co., Inc.

David Robinson received his BS in Chemical Engineering from the University of California at Berkeley and his Ph.D. in Chemical Engineering from the Massachusetts Institute of Technology and holds an adjunct faculty position in the Department of Chemical Engineering at Columbia University where he teaches a course on biochemical engineering.

David heads up the Bioprocess Research and Development group that is responsible for the process and analytical development for all biologics at Merck with recent successes including the successful licensure and approval of four new vaccines (ProQuad®, RotaTeq®, Zostavax® and Gardasil®), as well as the recent entry into the clinic of two new cancer antibodies.



Rich Soll, PhD
VP of Medicinal Chemistry, WuXi Apptech

Dr. Richard M Soll is currently Vice President, Medicinal Chemistry at WuXi AppTec. Previously he was the Chief Scientific Officer and Vice President, R&D at the San Diego based company TargeGen where he led innovative clinical-stage drug discovery and development programs for isoform-specific PI3K inhibitors as therapeutics for inflammation, respiratory disease and cancer, multitargeted src/VEGF inhibitors as the first topical kinase inhibitors for age-related macular degeneration and highly selective JAK2 inhibitors for the treatment of myeloproliferative disorders. Dr. Soll was the Vice President of Chemistry at Ontogen and also founded the chemistry department at 3-Dimensional Pharmaceuticals where he served as Vice President, Chemistry.

Dr. Soll's drug discovery and development experiences span numerous clinical indications and cover a wide range of molecular targets including inhibitors of kinases, serine proteases, GPCRs and protein-protein interactions. Through his contributions more than 6 clinical compounds have entered the clinic for cardiovascular disease, cancer, and ocular indications.

Dr. Soll serves as a scientific advisory board member to biotech companies and advisor to investors, and has extensively published in peer reviewed journals and is an inventor of numerous issued and pending patents.



Larry Wang, PhD
President, GenScript Corporation

Dr. Larry Wang is the co-founder and President of GenScript, a biology CRO company based in New Jersey, USA with manufacturing sites at Nanjing, China. The CRO service of GenScript is focused on early drug discovery. GenScript provides services ranging from molecular biology, protein expression, peptide synthesis, antibody production, to assay development.

Prior to GenScript, Dr. Larry Wang worked as a Senior Principal Scientist at Bioinformatics Group of Schering-Plough from 1996 to 2002. He is one of the key inventors on the target discovery work for Zetia, which advances the understanding of intestinal cholesterol pathway. His scientific achievement has been recognized with a presidential award by Schering-Plough, and Gallo Award from Cancer Research Institute of New Jersey.

Prior to Schering-Plough, Dr. Larry Wang got his Ph. D. from Rutgers University in 1996, and his BS degree in Biochemistry from Shandong University, China in 1991. Dr. Larry Wang has over 20 publications in leading scientific journals.



Chi-Huey Wong, PhD
President, Academia Sinica

Professor Wong received his B.S. (1970) and M.S. (1977) degrees from National Taiwan University, and Ph.D. (1982) in Chemistry from Massachusetts Institute of Technology. He then worked at Harvard University as a postdoctoral fellow for another year. He started his independent career as Assistant Professor of Chemistry at Texas A&M University in 1983, became Associate Professor in 1986 and Professor in 1987. He was Professor and Ernest W. Hahn Chair in Chemistry at the Scripps Research Institute (1989-2006) and Director of the Genomics Research Center at Academia Sinica, Taipei (2003-2006). Since October 2006, he has been President of Academia Sinica and Professor of Chemistry at the Scripps Research Institute and National Taiwan University.

Professor Wong is a recipient of The Searle Scholar Award in Biomedical Sciences (1985), the Presidential Young Investigator Award in Chemistry (1986), the American Chemical Society A. C. Cope Scholar Award (1993), the Roy Whistler Award of the International Carbohydrate Organization (1994), the American Chemical Society Harrison Howe Award in Chemistry (1998), the American Chemical Society Claude S. Hudson Award in Carbohydrate Chemistry (1999), the International Enzyme Engineering Award (1999), the Presidential Green Chemistry Challenge Award (2000), The American Chemical Society Award for Creative Work in Synthetic Organic Chemistry (2005), and the FA Cotton Medal (2008).

He is a member of Academia Sinica, Taipei (1994), the American Academy of Arts and Sciences (1996), the US National Academy of Sciences (2002) and the Academy of Sciences for the Developing World (TWAS) (2007). He serves as an Editorial Advisory Board member

for the Journal of American Chemical Society, Advanced Synthesis and Catalysis, and Current Opinion in Chemical Biology. He is currently Editor-in-Chief of Bioorganic and Medicinal Chemistry. He was Chairman of the Executive Board of Editors of the Tetrahedron Publications (2006-2008), head of the Frontier Research Program on Glycotechnology at RIKEN (Institute of Physical and Chemical Research, Japan, 1991-1999), and a board member of the US National Research Council on Chemical Sciences and Technology (2000-2003). He is currently a scientific advisor of the Max-Planck Institute (2000-), a member of Board of Directors of National Science Council, Taiwan (2008-present), and the chief scientific advisor of Executive Yuan, Taiwan (2008-present).

His research interests are in the areas of bioorganic and synthetic chemistry and biocatalysis, including development of new synthetic chemistry based on enzymatic and chemical reactions, synthesis of complex carbohydrates, glycoproteins and small-molecule probes for the study of carbohydrate-mediated biological recognition, post-translational glycosylation, and drug discovery. He is the author and co-author of over 600 publications, 60 patents, and four books (Enzymes in Synthetic Organic Chemistry, Combinatorial Chemistry in Biology, Catalysis from A to Z, and Carbohydrate-Based Drug Discovery).



Herren Wu, PhD
Vice President, Global Head of Technology and Lead Generation, MedImmune

Dr. Herren Wu is vice president of R&D, global head of technology and lead generation, and head of antibody discovery and protein engineering in MedImmune. In this position, he is responsible for new technology, antibody discovery, antibody/protein engineering, production cell line generation, structural biology and protein mimetics. He leads a global organization of about 160 scientists. He is actively involved in developing MedImmune's clinical- and preclinical-stage product candidates, and also participates in target discovery and validation for early research projects. He plays an essential role in discovering and developing an anti-RSV mAb, motavizumab that is currently under FDA review for market approval.

Dr. Wu has about 20-year experience in antibody discovery and protein engineering. He started as director, protein engineering and structure in MedImmune in 2002. Prior to joining MedImmune, he served as head, molecular biology department at Tanox, Inc. (acquired by Genentech in 2007). Before joining Tanox, he held a variety of research positions up to associate director, antibody engineering and discovery at Applied Molecular Evolution (now a subsidiary of Eli Lilly & Co.). He is the recipient of the Senior Technology Fellow Emerald Honors award presented at the 2006 Minorities in Research Science Conference. He is also named as co-inventor on 9 issued patents and 42 patent applications related to antibody technology and antibody/protein therapy.

Dr. Wu received his bachelor's degree in chemistry from the National Taiwan University and his doctorate in molecular and cellular biology from the University of Massachusetts, Amherst. He completed his postdoctoral training at The Scripps Research Institute in La Jolla, California.



Augustine Yee, JD
Senior Director, Global Strategic Planning and Business Development, AstraZeneca

Mr. Yee represents AstraZeneca's global and U.S. organizations across a wide range of corporate business development activities including strategic planning, late-stage product in-licensing, mergers and acquisitions and divestments for AstraZeneca's oncology, respiratory, inflammatory disease, neuroscience and anti-infectives businesses.

Mr. Yee has over 18 years of experience in the pharmaceutical and life sciences industry and has served on the senior management teams of both large pharmaceutical and small biotechnology companies. He has successfully orchestrated a wide range of multi-million dollar transactions including early, late stage and on-market therapeutic deals, mergers and company acquisitions, venture capital financings and initial public offerings.

Prior to joining AstraZeneca, Mr. Yee served as Vice President of Business Development at Archemix Corp., an aptamer therapeutic company based in Cambridge, Massachusetts. He has also held executive roles including Vice President of Business and Corporate Development at Prometheus Laboratories in San Diego, California and Senior Vice President of Corporate Development and General Counsel at Deltagen. Previously, Mr. Yee was a patent and intellectual property attorney with the patent law firm of Lyon and Lyon and a corporate securities attorney with the international law firm of Pillsbury Winthrop in their biotech and pharmaceutical company practice group. He received his degree in Molecular Biology from the University of California, San Diego and his law degree *magna cum laude* from the Pepperdine University School of Law.



Ray Yin, PhD

Founder & CEO, ANP Technologies, Inc.

Dr. Ray Yin is the founder and Chief Executive Officer of ANP Technologies, Inc. in Newark, Delaware (www.anptinc.com). Dr. Yin has played a vital role in ANP Tech's organic growth since its inception in 2002. The company currently provides cutting-edge technology solutions to customers in various market sectors such as rapid pathogen detection, medical diagnostics, biological drug development and testing.

Before founding ANP, Dr. Yin was the team leader/program manager for the nanobiotechnology program at the U. S. Army Research Laboratory (ARL). While at ARL, Dr. Yin successfully directed a number of basic research and rapid prototyping programs in the chemical and biological defense area, resulting in the U. S. Army R&D Achievement Award in 1999, 2000, and 2001. Dr. Yin was a scientific advisor to a variety of DoD programs and committees including DARPA, the Joint Service Agent Water Monitor program (JSAWM), the U.S. Army Edgewood Chemical and Biological Center (ECBC), the U.S. Army Research Office (ARO), the Office of Naval Research (ONR), the U.S. Army Center for Environmental Health Research (CEHR), and the U.S. Army Medical Research Institute for Chemical Defense (MRICD).

Prior to his ARL career, Dr. Yin was instrumental in developing, marketing, and licensing a number of nanomaterials-based technologies to a variety of companies while working in the private sector. Dr. Yin has published more than 40 papers and holds 12 U. S. patents. Dr. Yin received his Ph.D. in chemistry from the University of Southern California.



Han-Cheng Zhang, PhD

Vice President, Medicinal Chemistry, Shanghai ChemPartner

Prior to joining ChemPartner in December 2007, Han-Cheng spent 16 years in drug R&D with Johnson & Johnson and led several drug discovery programs with notable accomplishments in the areas of GPCR antagonists, protein kinase inhibitors, and protease inhibitors for drugs to treat cardiovascular diseases, metabolic diseases, cancers, etc. He is a key inventor on 33 patents (issued and pending), an author on >120 publications/presentations/meeting abstracts, a reviewer for a number of major international scientific journals, and an invited speaker for numerous international biotech/pharma conferences/forums/symposia. He is currently serving as Visiting Professor of Shanghai Institute of Materia Medica, Chinese Academy of Sciences, and Board of Directors and Immediate-Past President of SAPA-Headquarters. He was one of the key founders of SAPA-GP and served as 2004-2005 President of SAPA-GP. He earned B.S. and M.S. degrees in Chemistry from Xiamen University, and a Ph.D. degree in Organic Chemistry from Rensselaer Polytechnic Institute.

Job Openings at Participating Companies or Agency

To all applicants:

Please submit your CV to sapa@sapa.com prior to the conference for potential on-site interviewing opportunities
Hiring companies will have representatives at the Career Forum & Job Fair.



Research Scientist

ANP Technologies, Inc., a leading nanobiotechnology company, is seeking a research scientist to develop and run immunoassays and related tests for preclinical and clinical (PK/TK) studies for biologic drugs. MS or Ph.D. degree in relevant biochemical sciences with 4 years' industrial experience in ELISA assay development and clinical sample testing under GLP conditions are required.

ANP Technologies, Inc., 824 Interchange Blvd, Newark, DE 19711. Email: info@anptinc.com, Phone: (302) 283-1730.



Excel PharmaStudies, Inc. is a full-service provider of clinical research, registration, biometrics, and training and consultation services. Excel is the leading CRO in China. With 17 offices worldwide, nearly 300 staff members, and experience working with over 120 of the world's leading global pharmaceutical and biotech companies. Excel PharmaStudies, Inc. has the resources, connections, and expertise needed to help you with all of your drug development needs in Asia.

Job Description for Senior SAS Programmer

Performs all SAS programming tasks for a given clinical study or studies involving drugs, biologics and medical devices, acts as the primary point of contact for SAS programming activities for a given clinical study or studies and ensures adherence to guidelines, methodology and SOPs for software development in accordance with FDA, ICH, GCP and SDLC methodology; and provides technical support to the programming team.

Responsibilities

- Develops SAS programs to produce data listings and Case Report Form Tabulations (CRT) as by domain or by subject
- Builds standard tabulation datasets according to certain industry standard or the client's requirements
- Creates derived or analysis datasets according to certain industry standard or the client's requirements based on the statistical analysis plan
- Reviews the standard tabulation datasets and/or analysis dataset development specifications and SAS programs created by other SAS programmer(s)
- Develops SAS programs to implement statistical analyses and generate tables, listings and figures as specified in the statistical analysis plans
- Performs validation of and quality assurance aspects of all SAS programming activities
- Supports for regulatory submission (e.g. NDA and PMA) including submission datasets preparation
- Develops SAS programs for other needs
- Represents SAS programming team at project team meetings and provides updates to project team on status of tasks
- Communicates with project team members such as Project Biostatistician, Data Manager, and Project Manager regarding project issues
- Communicates with client regarding SAS programming issues
- Ensures integrity of all systems by preserving security and following change control procedures
- Participates in department level applications such as SAS Macro Library Development
- Consults on other statistical programming tasks, such as support for CRF design, database development, data validation plan and blinded data review
- Consults on SAS program design strategies and provides technical support to programming team
- Mentors and trains low level biostatisticians and new colleagues
- Performs other duties assigned by supervisor

Qualifications

- Bachelor degree in a scientific or technical area (statistics or related subjects is preferred); An advanced scientific degree is desirable
- Knowledge of programming methodology; a high degree of skills in the management and resolution of SAS programming issues
- At least 3 years (for bachelor) or 2 years (for master or above) experience with Base SAS (data step programming), SAS/SQL, SAS/MACRO, SAS/ODS, SAS/GRAPH, SAS/ACCESS and SAS/STAT. ISS/ISE experience is a plus
- Experience with the CDISC data standards and clinical database setup is preferred
- Experience of international drug development in a multicultural environment is a plus
- Ability to deal with sensitive inquiries or complaints from clients or potential clients and to protect confidentiality

- Demonstration of ethical leadership skills and exhibit high moral character so as to foster respect for ethnic and religious diversity and support equal opportunity for all employees based on demonstrated ability and to exhibit a high degree of skills in the management and resolution of conflict
- Knowledgeable in all aspects of the drug agencies (e.g. FDA) regulations and requirements governing the conduct of drug, biologic and device studies including, but not limited to, GCP and ICH requirements
- Excellent communication and interpersonal skills
- Able to make effective presentations in public settings
- Proficient working in a PC/Windows environment

A good command of English language if one's native language is not English

Job Description for Project Manager of Clinical Operations

Responsibilities:

- Coordinate and supervise all aspects of implementing and conducting clinical studies in accordance with SFDA regulations, GCP/ICH guidelines, and Excel's/sponsor's SOPs.
- Coach CRAs in a specific area.
- Provide recommendation to CRAs in working skills and people development.
- Contribute to the development of protocols and CRFs.
- Ensure protocol compliance across all sites.
- Participate in site selection, initiation, monitoring, and closure activities.
- Generate clinical project plan including timeline projection and monitoring strategy.
- May function as a project leader coordinating multi-functional project teams, may be involved in budgeting and contracts.
- Review of CRA trip reports and correspondence.
- Preparation and implementation of project-specific training programs and presentations for internal and external clinical team.
- Provide leadership, guidance and mentoring to clinical team.
- Generate regular written status reports for both internal and external use.
- Maintain awareness of developments in the field of clinical research, GCP, and therapeutic area.
- Make recommendations regarding monitoring safety, eligibility, enrollment, and data consistency. Organization and participation in investigator meetings, including presentations.

Qualifications:

- A Bachelors Degree in a medical, health, or science related area; MS/MD preferred.
- Minimum of 3-5 years experience in clinical research or clinical trial monitoring as a CRA in a pharmaceutical or a CRO company.
- Minimum 2 years experience in clinical trial management.
- Proficient in SFDA regulations and GCP/ICH guidelines.
- Knowledge of the medical, scientific and clinical research aspects of pharmaceutical trials.
- Knowledge and experience in clinical trial design, analysis and reporting, advanced clinical/pharmacology training preferred.
- Demonstrated ability to write protocols, CRFs, and clinical trial reports independently.
- Demonstrated ability to plan and organize effectively. Demonstrated ability to identify and solve problems independently.
- Mentor and support clinical research staff.
- Effective oral and written communication skills in English are a must. Excellent computer literacy.
- Self-motivated and positive team player.
- Must be able to travel if required.



WuXi AppTec is Hiring Talent

WuXi AppTec is a leading global pharmaceutical, biopharmaceutical and medical device outsourcing company with operations in China and the United States. As a research-driven and customer-focused company, WuXi AppTec provides a broad and integrated portfolio of laboratory and manufacturing services across the discovery-to-commercialization spectrum. Our services are designed to assist our customers worldwide in shortening the time and lowering the cost of drug and medical device R&D by providing cost-effective and efficient outsourcing solutions. Our rapid business expansion opens up the exciting positions as follows:

Biology:

Executive Director In Vivo Biology, Metabolic Disease-Shanghai

Qualifications: An experienced individual to in vivo biology efforts to support medicinal chemistry programs at the company. Industrial in vivo biology experience and good communication skills are required. A Ph.D. in pharmacology, physiology or a related discipline with at least several years experience and a record of accomplishments are essential.

Responsibilities: lead multiple groups of in vivo biologists working on animal model development, validation and execution, and data management.

Executive Director In Vivo Biology, Oncology-Shanghai

Qualifications: An experienced individual to in vivo biology efforts to support medicinal chemistry programs at the company. Industrial in vivo biology experience and good communication skills are required. A Ph.D. in pharmacology, physiology or a related discipline with at least several years experience and a record of accomplishments are essential.

Responsibilities: lead multiple groups of in vivo biologists working on animal model development, validation and execution, and data management.

Executive Director In Vivo Biology, CNS-Shanghai

Qualifications: An experienced individual to in vivo biology efforts to support medicinal chemistry programs at the company. Industrial in vivo biology experience and good communication skills are required. A Ph.D. in pharmacology, physiology or a related discipline with at least several years experience and a record of accomplishments are essential.

Responsibilities: lead multiple groups of in vivo biologists working on animal model development, validation and execution, and data management.

Executive Director/Senior Director, Virology-Shanghai

Qualifications: An experienced individual to lead anti-viral drug discovery biology efforts at the company. Industrial screening experience and good communication skills are required. A Ph.D. in biochemistry, molecular biology or virology with about 10-15 years experience and a record of accomplishments in virology and drug discovery research are essential.

Responsibilities: lead multiple groups of scientists working on assay design, development, optimization, validation and execution, and data management.

Senior Director/Director/Associate Director, Enzymology - Shanghai

Qualifications: An experienced individual to lead enzyme-targeting biochemical screening efforts at the company. Industrial screening experience and good communication skills are required. A Ph.D. in biochemistry with at least several years experience and a record of accomplishments in enzymology are desired.

Responsibilities: lead multiple groups of biochemists working on assay design, development, optimization, validation and execution, and data management.

Senior Director/Director/Associate Director, Discovery Biology - Shanghai

Qualifications: An experienced individual to lead biochemical and cell-based screening efforts to support medicinal chemistry programs at the company. Industrial screening experience and good communication skills are required. A Ph.D. in biochemistry or cell biology with at least several years experience and a record of accomplishments are desired.

Responsibilities: lead multiple groups of biochemists and cell biologists working on assay design, development, optimization, validation and execution, and data management.

Senior Director/Director/Associate Director, High Throughput Screening - Shanghai

Qualifications: An experienced individual to lead high throughput biochemical and cell-based screening efforts at the company. Industrial high throughput screening experience and good communication skills are required. A Ph.D. in biochemistry or cell biology with at least several years experience and a record of accomplishments are desired.

Responsibilities: lead multiple groups of biochemists and cell biologists working on assay design, development, optimization, validation and execution, and data management.

Synthetic Chemistry:

Vice President of Medicinal Chemistry - Shanghai

Qualifications: An accomplished and innovative individual with a Ph.D. degree in Organic or Medicinal Chemistry along with at least 15 years of working experience and at least 12 years of experience in project management and at least 10 years of experience in leading medicinal chemistry programs. Expertise in GPCR and/or kinase target classes is preferred. An outstanding publication record and great accomplishments in discoveries of novel drug candidates are must-have qualifications

Executive Director/Senior Director/Director of Medicinal Chemistry - Shanghai

Qualifications: An accomplished and innovative individual with a Ph.D. degree in Organic or Medicinal Chemistry along with at least 10 years of working experience in pharmaceutical industry. Great problem solving ability is a must-have quality. An outstanding publication record and great accomplishments in medicinal chemistry and familiarity with GPCR or kinase, protease or ion channel targets are desired.

Project Team Leader of Medicinal Chemistry - Shanghai

Qualifications: An accomplished and innovative individual with a Ph.D. degree in Organic or Medicinal Chemistry along with 3-5 years of working experience in pharmaceutical industry. Great problem solving ability is a must-have quality. An outstanding publication record and great accomplishments in medicinal chemistry and familiarity with GPCR or kinase, protease or ion channel targets are desired.

Principle Scientist/Senior Scientist of Medicinal Chemistry - Shanghai

Qualifications: Fresh Graduate with Ph.D. degree in Organic or Medicinal Chemistry is required for Sr. Scientist. Additional 2-3 years Postdoctoral research experience after Ph.D is required for Principle Scientist.

Manufacturing:

VP for Pre-formulation/formulation - Shanghai

Qualifications: Broad experience with proven track records, and +10 years industrial experience are required.

Responsibilities: To lead the department working on technical support to later discovery activities, process development activities, formulation development and manufacturing activities, and lead the department to interact closely with the clients and provide effective plans to move the programs quickly to achieve the objectives.

Ex./Sr./Director of Formulation development - Shanghai

Qualifications: An accomplished and innovative individual with a Ph.D. degree in Pharmaceuticals along with at least six years of hands on working experience (after obtaining Ph. D. degree) and/or at least 5 years of experience in project management. Alternately, an individual with a Masters degree in Pharmaceuticals with at least eight to ten years hands on working experience with at least 3 years experience in project management. The candidate must have a demonstrated record of accomplishments in formulation development of solid and liquid oral dosage forms from initial phase to scale up for technical transfers. Additional experience with other dosage forms will be an added asset. Problem solving ability and adept handling of formulation teams is a must-have quality. Experience of working across cultures would be an added benefit.

Responsibilities: To lead multiple groups of formulators working on different types of solid and liquid oral dosage forms. To plan and monitor projects, prepare project reports and interface with clients.

Sr./Director of Pre-formulation development - Shanghai

Qualifications: An accomplished and innovative individual with a Ph.D. degree in Physical Chemistry/ Physical pharmacy along with at least six years of hands on working experience (after obtaining Ph. D. degree) and/or at least 5 years of experience in project management.

Alternately, an individual with a Masters degree in Physical Chemistry with at least eight to ten years hands on working experience with at least 3 years experience in project management. The candidate must have a demonstrated record of accomplishments in pre-formulation activities of solid and liquid oral dosage forms. Problem solving ability and adept handling of pre-formulation teams is a must-have quality. Experience of working across cultures would be an added benefit.

Responsibilities: To lead multiple groups of pre-formulators working on different types of activities for solid and liquid oral dosage forms. To plan and monitor projects, prepare project reports and interface with clients

Senior Director/Director of Process Chemistry - Shanghai

Qualifications: An experienced individual to lead multiple group of process chemists working on the process design, process optimization and scale-up in the GMP plant. Good communication skill and strong organic synthesis knowledge are required. A Ph.D. in chemistry with at least 5 years' experience and a record of accomplishment in chemistry are desired. Significant experience in an industry environment as leader will be ideal.

Responsibilities: lead multiple group of Process Chemists working on the process design, process optimization and scale-up in the GMP plant.

Principal Scientist of Analytical Development - Shanghai

Qualifications: PhD or MS in Analytical Chemistry or equivalent with a minimum of 3 years industrial experience for PhD and 5 years for MS in Analytical R&D functions for small molecule drugs - all aspects of analytical development and characterization for both drug substance and drug product.

Responsibilities: The incumbent is responsible for leading the analytical research and development activities in all phases of drug development and interacting with other functions such as Process R&D, formulation development, Quality Assurance, CMC and regulatory affairs. The candidate should have strong scientific/technical expertise and deep experience in API or drug product development (e.g. analytical development for API or/and formulated products and experience in GMP compliance desirable).

Director of QC – JinShan, Shanghai

Qualifications: The candidate should have extensive technical/regulatory expertise and experience in all aspects of quality control of API or advanced intermediates (e.g. analytical method and specs development for API or/and formulated products, PAT technology, ICH guidelines and GMP compliance) appropriate for the level of decision making the job requires.

The qualified candidate should have PhD or MS degree in Analytical Chemistry or equivalent with 5~10 years industrial experience in small molecule pharmaceutical analysis (all aspects of drug substance or drug product analysis in GMP compliant analytical laboratories, preferably in QC laboratories).

Responsibilities: Lead the QC department activities within STA that interacts with other functions such as Production and Quality Assurance within STA and Analytical R&D and Process R&D in the R&D center.

Toxicology:

Study Director of Toxicology - Suzhou

Qualifications: Minimum: MS in toxicology or related fields (e.g. medicine, physiology, biology) and 5-10 years experience in nonclinical in vivo toxicological studies. Preferred: DVM/MD or PhD in in toxicology or related disciplines with more than 7 years experience in the pharmaceutical/biopharmaceutical industry or contract research organizations. Board certification in toxicology and Fluency in Chinese are desirable. Experience designing/conducting/monitoring toxicology studies. Experience in animal surgery, animal care, biology, and/or biomaterials desirable. Knowledge of GLP regulations and relevant FDA and ICH, guidelines for nonclinical safety testing highly desirable.

Responsibilities: Protocol design, IACUC submissions, study initiation and documentation, data analysis and interpretation, regulatory compliance, as well as reporting of study results. You will act as a key point of contact for all internal departments engaged in a study and develop strong working relationships with relevant external representatives to ensure the smooth flow of data to the client organization. You must pay attention to details, check that all data is appropriately recorded and compiled throughout the study, and accurately interpreted and documented in subsequent reports, and ensure that all studies are conducted in-line with GLP guidelines and regulatory test standards. You should have the ability to handle multiple studies and solve issues arising on a dedicated study.

Senior Director of Toxicology - Suzhou

Qualifications: DVM/PhD in toxicology or related disciplines with and more than 8 years experience in preclinical toxicology studies. Board certification in toxicology desirable. Experience in customer communications for the pharmaceutical industry/contract research organizations. Experience with conducting and monitoring toxicology studies. Experience in animal surgery, animal care, and biology desirable. Demonstrated strong leadership and management skills; business degree or experience desirable. Knowledge of GLP regulations and relevant FDA, ICH, and ISO guidelines

Responsibilities: protocol preparation, data sheet preparation, IACUC submissions, study conduct, data collection/documentation, draft report preparation, and assuring protocol, SOP, and regulatory compliance for toxicology studies. This position requires strong leadership, a high-level of attention to detail and time management, direct communications with clients and an ability to work across functions internally to plan, execute, and complete testing programs that meet Sponsor requirements. Other duties include in-life resource planning, maintaining current testing procedures, program development, performance monitoring, budget planning, and resource management. The Senior Director of Toxicology will represent WuXi AppTec and its preclinical safety testing programs externally and will interface between senior management and the toxicology department internally.

Veterinarian Ophthalmologist-Suzhou

Qualifications: A Ph. D. in ophthalmology with over 2 years experience in clinical ophthalmology.

Responsibilities: According to protocol and/or SOPs, perform laboratory animal ophthalmology examinations.

Develop, review, revise and implement related SOPs

Ensure compliance with laboratory regulations and assist with data management and record keeping.

Assisting planning, training, monitoring, and develop and review new procedures and technologies as required.

Attending Veterinarian-Suzhou

Qualifications: A Ph. D. in Clinical Veterinary Medicine with Over 3 years experience in attending veterinary. Familiar with clinical signs, behavior and care of large animals such as dog and NHP. In-depth knowledge of PRC and US laboratory animal law, regulations and guideline, AAALAC standards. Certificate of PRC laboratory animal care and use. Certificate of PRC Veterinary Medicine.

Responsibilities: According to PRC and US laboratory animal law, regulations and guideline, AAALAC standards, improve the standardization of the management of veterinary work.

Ensure that study protocols and conduct meet all requirements of US related laboratory animal regulations, guidelines and so on.

As a member of IACUC, review IACUC Protocol for animal study and oversee animal care and use. Ensure that the protocol is consistent with company guidelines and SOPs.

Develop, review, revise and implement SOPs relating to this position.

According to protocol or/and SOPs, perform laboratory animal acclimating, quarantine and physical examinations.

Periodic assessment of animal welfare.

Providing veterinary health care. Ensuring pain relief. Recommending endpoint of animal study and appropriate methods of euthanasia.

Assisting with pre-surgical planning, training, monitoring, and post-surgical care.

Develop and review new procedures and technologies as required, including development of new surgical procedures.

WuXi AppTec welcomes overseas talents join us. We offer you a highly competitive compensation and full benefits package along with an exciting world-class work environment in China. For more information, please visit our website: www.wuxiapptec.com.

For prompt consideration, please send your CV to: hr@wuxiapptec.com.



Positions of Roche R&D Center (China)

About Roche and Roche R&D Center (China)

At Roche, about 80,000 people across 150 countries are pushing back the frontiers of healthcare. Working together, we've become one of the world's leading research-focused healthcare groups. Our success is built on innovation, curiosity and diversity, and on seeing each other's differences as an advantage. To innovate healthcare, Roche has ambitious plans to keep learning and growing - and is seeking people who have the same goals for themselves.

Roche R&D Center (China) Ltd., the first drug discovery R&D center in China owned by a global healthcare company, was established in 2004. RRDC research team has also grown 20 medicinal chemists by end of 2004, to a team of over 80 research scientists by 2008, from different disciplines like biology, screening, medicinal chemistry, DMPK, molecular design and biostructure, as well as research technology, etc.

Though initially focused on medicinal chemistry research in lead generation and optimization, RRDC is operating under a new drug discovery model in China. Under this operation, DBA will approve the targets or assets that are brought into RRDC portfolio. Then, RRDC will have the decision rights across the value chain. Once proof of concept is realized in the clinic, SPC will decide to either bring or not bring that asset into the global portfolio. In this model, RRDC will maintain its core internal competency in house while flexibly rely on expertise of external partners.

RRDC will focus on diseases that are more prevalent in the Asia-Pacific Rim and bringing important drugs to the Chinese market as well as global market to meet the unmet medical needs.

Job location

Zhangjiang High-Tech Park, Shanghai, China

Contact

E-mail: shanghai.rdcrecruit@roche.com; Clevin.liu@roche.com

Position 1: Head of Formulation R&D

This position:

This position will drive the formulation elements of research and development for new compounds/technologies. In collaboration with both R&D and manufacturing, this formulations leader will be responsible for:

- identifying formulation research and development and/or delivery technology opportunities, evaluating/identifying technology leaders and CRO's; making recommendations to senior management
- executing the formulation research and development programs that provide the most value and positive impact to the drug portfolio
- managing the collaboration with third party vendors for outsourced activities and providing interim and final deliverables within reasonable time and budget constraints
- assisting in the integration of the technical "know-how", formulation(s), and/or processes into production of clinical trial material

Duties may include

- Significant first-hand experience in the early formulation research of NME for tox studies and early phase of clinical trials are highly desirable
- Provide expertise in the areas of traditional solid-dose unit operations; specifically, granulation, fluid-bed processing, blending, tableting, pan coating, encapsulation
- R&D and production knowledge of parenteral formulations, particularly IV formulation for tox and clinical studies are highly desirable
- Conduct comprehensive technical investigations and effectively troubleshoot issues in the area of pharmaceutical formulation R&D
- Writing and reviewing of protocols and final reports; performing project management, and data analysis.
- Supports cross-functional teams as an in-house formulation expert
- Equipment or facility validation (or other lab work) is required in this role. Prepare validation documents for new products for clinical trials in a cGMP regulated environment
- Relevant professional experience in cGMP manufacturing environment is preferred.
- Working knowledge of the FDA Guideline on General Principles of Process Validation and Quality System Regulations is preferred.
- Excellent communication and good organizational skills with the ability to multi-task is necessary

- Lead technology transfer of new projects and technologies within Roche or from/to CRO's
- Provide technical leadership in the areas of formulation and process knowledge to commercial manufacturing operations and QA
- Proactively identify and implement programs to improve the quality and/or efficiency of cGMP manufacturing operations

Who you are:

Ideal candidate will offer a Ph.D. degree in a related science as well as 4+ years of increasing responsibility and roles in formulation-ideally within both large pharma and biotech. Relevant first-hand experience in the area of formulation and process research and development of pharmaceutical solid/liquid dosage forms

Position 2: Research Investigator in Medicinal Chemistry Department

The Position:

- Serve as an expert in the field of medicinal chemistry and provide scientific evaluation and constructive recommendation to research project at different stage of drug discovery;
- Lead a research project/project chemistry team and be accountable to the outcome of project;
- Critically evaluate biology, DMPK, PK/PD and tox experiments/studies, and provide strategic directions for project/project chemistry utilizing those information;

Who you are:

- Ph.D. in organic chemistry or medicinal chemistry
- Proven track record in drug discovery research and advancing compounds successfully into clinic
- Over 5 years experience in pharmaceutical industry
- Expertise in following disease area is preferred: oncology, virology and metabolic diseases
- Excellent communication and presentation skills in English and Chinese

Position 3: Associate Investigator In Toxicology and Drug Safety

The Position:

- Design, perform and oversee non-clinical drug safety and toxicology studies including both in vitro and in vivo experiments to support drug discovery and development programs;
- Serve as in house expert and study director to coordinate external studies performed in CROs and academic institutes;
- Represent toxicology and drug safety in multidisciplinary project teams and help project teams to make decisions in early and late drug discovery and development programs;
- Lead or manage a group in drug safety evaluation
- Provide timely summary and report to project team and is responsible for the interpretation of study results

Who you are:

- Ph.D. in Toxicology or a related field with at least three years of experience as a toxicologist within the pharmaceutical industry;
- Comprehensive understanding of toxicology and non-clinical drug safety is essential; knowledge of drug metabolism and pharmacokinetics, statistics and physiology of animals (rat, dog, mouse, monkey and man) is a plus;
- Good communication and interpersonal skills;
- Must be able to work in a bilingual environment (English and Chinese);
- Strong leadership skills in manage project team or major tasks is a plus

Position 4: Senior Scientist in virology group

The Position:

- Possesses a knowledge base in current molecular virology;
- Utilizes scientific principles and experience to independently design and execute experiments in the process of discovery and validation of new molecular targets;
- Works with internal associates and external partners in assay development, primary and confirmative screen, lead generation and optimization, mechanism of action study, resistant profile and reverse genetics;
- Cooperates and communicates with scientists of other departments to ensure project progress;
- Organizes and presents experimental data; prepares scientific manuscripts for publication and patent applications;
- May be responsible for managing one or more associates according to previous experience.

Who you are:

- Candidates should hold a Ph.D. degree in virology, molecular biology or a related field;
- Should have 2-5 years working experience after obtaining the degree, antiviral or industry experience is a plus;
- Should be proficient in conducting experiments involving in virology, molecular biology, enzymology, and tissue culture techniques;
- Capable of fitting into a fast-paced, growing company environment with multi-tasks;
- Should be a team player as well as an independent researcher;
- Good communication and presentation skills both in English and Chinese.

Position 5: Senior Scientist in Metabolic Diseases Group

The Position:

- work as a member of multi-disciplinary team on drug discovery in metabolic diseases area.
- Design, develop and conduct cell-based assays for target validation and lead optimization.
- Design and conduct in vivo pharmacological study in small animal disease models
- Apply scientific knowledge to identify new drug targets
- Work with and manage other associates and external partners on related projects
- Conduct effective verbal and written communication with team and prepare reports for internal/external publication.

Who you are:

- PhD degree in cell biology, pharmacology or a related field;
- Solid knowledge in signal transduction, physiology, and intermediate metabolism
- Training in metabolic diseases is a plus
- Extensive experience in cell culture and cell-based assay development
- Experienced in small animal handling, and experimental design
- Capable to handle multi-tasks in a fast-paced growing company environment
- Excellent communication and presentation skills both in English and Chinese
- Self motivation and good team player

Position 6: Senior Scientist in Analytical department

The Position:

This position will provide analytical support for the early to late stage of drug development. The selected candidate will be responsible for the characterization, analysis and control of drug substance and drug products using various analytical techniques. Position responsibilities will include but not be limited to:

- Develop and validate analytical methodologies (assay, impurities etc.) for the clinical candidates, drug substances and drug products.
- Validate/evaluate analytical methods, analytical results and reports etc. from external partners; Draft/evaluate SOPs, test procedures and research protocols; Effectively communicate status, progress, and challenges internally and externally in written and verbal formats.
- May manage 1-2 internal analytical scientists and/or co-manage numbers of external full-time-employee (FTE). Working efficiently to support process chemistry, preformulation/formulation and manufacture with the internal and external efforts.
- Troubleshoot and calibrate analytical instrumentation; conduct equipment IQ/OQ/PQ to consistent with GMP/GLP compliance.
- Identify the quality of methods and data that flow in/out and provide the support in their resolution. Support methods and documentation transfer activities.

Who you are:

- Firm knowledge of analytical chemistry, pharmaceutical analysis, and of pharmaceutical regulatory requirements. Strong experiences in chromatographic and spectroscopic method development and validation, such as HPLC, GC, IR, LC/MS and other quality control equipments.
- Well developed written, oral and interpersonal skills and able to work in a team, well communication with customers and partners. Capable of designing experiments, drafting protocols, generating data and interpreting results independently.
- Ph.D. degree plus at least 2 years of industrial experiences or MS with at least 6 years experiences is required. Has working experiences in cGMP/GLP environment or experience with handling IND/NDA of SFDA/FDA is plus.

Position 7: Senior scientist in macromolecular x-ray crystallography

This position:

An experienced structural biologist in the field of x-ray crystallography, reporting to the head of molecular design and biostructure. You will be responsible for setting up an x-ray crystallization lab, performing protein crystallization including co-crystallizing and soaking small molecules, as well as structural determination of protein-ligand and/or protein-protein complexes. You will work closely with our biostructure collaborators in both the CRO companies and academic labs. You will be part of the molecular design and biostructure team, working closely with computational chemists and medicinal chemists to apply structural information in lead generation and optimization.

Who you are:

- Ph.D. in protein x-ray crystallography.
- At least two years of post doctoral experience in protein structure determination, preferably in protein-protein and/or protein-small molecule complexes.
- Highly experienced in protein crystallization, protein and crystal handling, data collection using synchrotron and in-house equipment, and structure refinement.
- Experience in expression construct design and protein purification.
- Experience with protein biochemical and biophysical characterization.
- Experience in supervising x-ray crystallography lab including hardware and software is desired.
- Experience in structure-based drug design is a plus.
- Familiarity with other structural biology methods, e.g. NMR and EM, is a plus.
- Ability to be multitasking, manage multiple projects, and work on a timeline.
- Excellent oral and written communication skills as well as good presentation skills is a must.

For more position information, you can also find it through: www.51job.com or <http://careers.roche.com>.



Open Positions for Fountain Medical Development

1. Business Development Manager

Fountain Medical Development, is a full service contract research organization. We are specialized in conducting and managing clinical studies in China. Our clients include multi-national pharmaceutical companies as well as biotechnology firms in USA and/or Europe.

As numerous drug development studies are being outsourced to Asia and China, this position offers high level of career growth potential and an accelerated path to gain insider knowledge of a) drug development processes and b) managing critical studies for pharmaceutical and biotech industry. It provides opportunity to obtain cross-cultural business management skills (Western culture vs Asian culture).

We also offer trainings on regulatory aspect of drug development, including (GCP) good clinical practice, (GLP) good laboratory practice, and ICH guidelines for clinical studies.

Job Description:

- 1) Responsibilities:
 - Customer relations: Contacting pharmaceutical companies and/or biotechs in US. Establishing and managing working relationships with senior management of research and development departments.
 - Preparing communication materials for clients, including reports as well as presentation materials. Answer clients' needs by emails, fax or phone calls.
- 2) Reporting relationship:
Reports to VP, Business Development
- 3) Office location: Home based in NJ/PA/NY, USA
- 4) traveling: 20% initially, Attending professional conferences (BIO, DIA meetings, etc) and visiting potential clients on-site
- 5) Full-time positions.
- 6) Starting time: Sept 1, 2009
- 7) Requirement:
 - A valid driver's license
 - Working permit in United States
 - Ability to work independently, initiate contact and develop clients and contracts
 - At least four years of business development or sales experience in CRO
 - Familiarity with Chinese regulatory and clinical study process and environment is a plus
 - MS or MA in Biology, Medical sciences or MBA preferred.
 - Expert in using MS words, MS Excel, MS power points. Knowledge of using MS project is a plus
 - Excellent communication skills, verbally and written
 - Basic knowledge of clinical trial processes
 - Good analytical thinking
 - Excellent work ethics, detail-oriented
 - Excellent people skills, flexible, easy to interact with

Please contact Joanne Jiang at joanne.jiang@fountain-med.com or 732-447-6898, if you are interested.

2. International Project Manager

Fountain Medical Development, is a full service contract research organization. We are specialized in conducting and managing clinical studies in China. Our clients include multi-national pharmaceutical companies as well as biotechnology firms in USA and/or Europe.

As numerous drug development studies are being outsourced to Asia and China, this position offers high level of career growth potential and an accelerated path to gain insider knowledge of a) drug development processes and b) managing critical studies for pharmaceutical and biotech industry. It provides opportunity to obtain cross-cultural business management skills (Western culture vs Asian culture).

We also offer trainings on regulatory aspect of drug development, including (GCP) good clinical practice, (GLP) good laboratory practice, and ICH guidelines for clinical studies.

Job Description:

- 1) Responsibilities:
 - Managing ongoing clinical trial projects. Prepare reports, communication as well as proposals for clients
 - Interacting with operation team in China and Asia, obtain updates and participate teleconferences
 - Present proposals and company capability presentations at client sites
- 2) Reporting relationship:
Reports to VP, International Project Management
- 3) Office location: Home based in NJ/PA/NY, USA
- 4) Traveling: 5-10%. Attending professional conferences (BIO, DIA meetings, etc) and visiting potential clients on-site
- 5) Full-time position.
- 6) Starting time: Sept 1, 2009
- 7) Requirement:
 - A valid driver's license
 - Working permit in United States
 - Ability to work independently, managing project teams and deliverables as well as timelines.
 - At least four years of project management experience in CRO
 - Familiarity with Chinese regulatory and clinical study process and environment is a plus
 - MS or MA in Biology, Medical sciences, PhD preferred.
 - Expert in using MS project, MS words, MS Excel, MS power points.
 - Excellent communication skills, verbally and written
 - Strong knowledge of clinical trial processes
 - Strong knowledge of ICH GCP standards
 - Good analytical thinking
 - Excellent work ethics, detail-oriented
 - Excellent people skills, flexible, easy to interact with

Please contact Joanne Jiang at joanne.jiang@fountain-med.com or 732-447-6898, if you are interested.



1. VP of Biology

2. Director of Business Development (California)

Description: The role of Business Development Director will be responsible for our key accounts, and for developing business relationship with biotech and pharmaceutical companies, and establishing strategic relationship with potential partners and companies. The position is primarily responsible for accounts in our USA Western Sector (California and nearby states).

Requirements: * At least 2 years direct sales, preferable solution sales in biology markets * Ability to interact with C-levels, decision makers * Excellent presentation and communication Skills * Experiences in early drug discovery is preferred, particularly in assay development, HTS screening, reagent procurement, and CRO management. * Strong education background in life sciences.

Please send your Resumes and Cover Letter to

hr@genscript.com



Waterstone Pharmaceuticals, Inc.

Waterstone Pharmaceuticals, Inc. is a US-based company with state-of-the-art chemical manufacturing facilities in China. We have just closed a \$12 million venture capital financing and an API manufacturing facility which will meet the USFDA and the ICH cGMP requirements is under construction in Wuhan, China,. We are searching for a General Manager to oversee API facilities construction, production and related commercial operations.

CANDIDATE REQUIREMENTS

- 5+ years in pharmaceutical industry with cGMP experience;
- Experience in API manufacturing facility design/management is desirable;
- Technical and/or production background in API or drug formulation;
- Deep familiarity with Drug Master Files (DMF) filing.
- familiarity with Quality Assurance and Quality Control and the management of these departments
- Senior management experience and responsibilities including budget creation and resource allocation;
- Effective leadership skills to think, lead, motivate and execute in a team effort;;
- Excellent Mandarin and English language skills;

JOB DESCRIPTIONS

- Full P&L responsibility for the API operations, including facilities construction, production and commercial operations;
- Responsible for development of management team and operating procedures;
- Secure and maintain cGMP certification;
- Introduce QMS manufacturing practices; maintain and improve QA/QC standards; comply with cGMP and other health and safety regulations;
- Responsible for overall success of commercial operations through establishment of the sales team, distributors' network, among others;
- External relationship building and maintenance with global customers.

Waterstone Pharmaceuticals provides our employees with competitive salary and compensation package, which includes bonus and stock options. We are also searching for director positions on QA, regulatory, process chemistry. Qualified candidates are encouraged to submit your CV to fzhang@waterstonepharma.com



M · T · T · I

MOLECULAR TARGETING TECHNOLOGIES, INC.

Postdoctoral Research Position Available at Molecular Targeting Technologies, Inc.

Job Title: Chemistry Postdoctoral Associate. Reports to the VP of Research

Overview: MTTI is seeking a highly motivated candidate with a strong background in fluorescent dye chemistry and bioconjugation techniques to join its team. Additional experience in the areas of nanoparticle or quantum dot chemistry is particularly preferred. This position is for a period of 1 year initially which may be extended upon mutual agreement.

Responsibilities:

- (1) Plan, design and perform experiments in consultation with supervisor aimed at the preparation of novel fluorescent dyes using advanced and basic lab skills in synthetic organic chemistry.
- (2) Characterize the properties of dyes using spectroscopic and HPLC techniques.
- (3) Prepare/assist in the preparation of SBIR grant proposals
- (4) Resupply compounds of interest using established and/or modified protocols as needed.
- (5) Write protocols and maintain complete and thorough lab notebook.
- (6) Make detailed observations, analyze data and interpret results.
- (7) Maintain laboratory equipment and supplies needed in performance of experiments.
- (8) Contribute ideas and suggestions to improve protocols and techniques.
- (9) Comply with all company safety regulations and procedures to maintain a safe and clean laboratory environment.
- (10) Provide written reports and protocols to supervisor.

Requirements:

- (1) PhD (Chemistry) and experience performing synthetic organic chemistry with fluorescent dyes.
- (2) Experience in nanoparticles/quantum dot and bioconjugation methods a plus.
- (3) Experience with HPLC and fluorescence spectroscopy preferred.
- (4) Effective oral communication skills and ability to troubleshoot.
- (5) Excellent writing skills.
- (6) Excellent time management skills required.
- (7) Strong attention to detail, self-motivation and developed organizational skills.

Work Conditions:

Works in a lab environment. Is required to lift up to 40lbs. Must be able to work safely with hazardous chemicals.

EOE Employer

We offer competitive salaries, excellent benefits and an opportunity for professional development in a small dynamic company environment

To Apply:

Those interested should submit a cover letter and resume to the following address, fax or email:

Dr. Brian Gray, VP Research
Molecular Targeting Technologies, Inc.
833 Lincoln Ave. Unit 9, West Chester, PA 19380
Fax: 610 738 7928, briangray@mtarget.com

**Job Description: Associate Director/Director – Formulation Development (China Operation)**

We are looking for an **Associate Director/Director of Formulations Development** to join a highly respected and growing Contract Research Organization. It is a Senior level Scientific Leader position who through continuous technical, process, and quality improvement, is responsible for the development of a broad spectrum of dosage forms including tablets, capsules, SR formulations, oral liquids, topical preparations and parenteral formulations as well as clinical dosage form manufacturing.

This position offers a unique opportunity to interact with a variety of Pharmaceutical companies seeking to outsource preformulation, formulation, and process development research studies; and influence the development of a wide array of pharmaceutical drug candidates in a contract development and manufacturing environment.

This position requires the incumbent to possess and maintain an understanding of both scientific and regulatory requirements in the areas of responsibility. A solid technical background and an understanding of compliance standards, gained through either experience or education, is required, as is an understanding of cross-functional areas such as plant operations, quality and regulatory affairs.

The primary function of this position is to supervise/guide and coordinate the work of the professionals and technicians in the department to ensure successful completion of all activities assigned.

MAJOR ACTIVITIES:

- Understand and mentor teams on the customer needs.
- Design strategies for developing various dosage forms including conventional and novel drug delivery systems.
- Support process optimization studies and tech transfer to internal or external stakeholders for CGMP clinical and/or commercial manufacturing.
- Work with Project Management teams to collaboratively manage the successful execution contract formulation development deliverables including proposal writing, project planning, timeline review, project kick-off and update meetings, coordination with other scientific groups, and providing direction to associates to achieve revenue targets and accomplish business objectives
- Hiring, training and leading Formulation staff
- Coordinate the resources to ensure timely completion of projects.
- Participate in defining new products and strategies through the business team, as appropriate
- Participates in the incorporation of knowledge of current regulations, guidance's and competitive environment into decisions and strategy.

QUALIFICATIONS:

- PhD in pharmaceutical sciences that provides relevant experience for clinical and commercial development of pharmaceutical drug products.
- The individual must have a fundamental understanding of pre-formulation, stability, formulation development, analytical and regulatory process.
- 15+ years of industrial experience in formulation development.
- Published research in peer reviewed journals and presentations at national/internal conferences is expected.
- Experienced in working in a GMP/GLP environment.

ADDITIONAL SKILLS/PREFERENCES:

- Ability to influence projects.
- Excellent communication skills, both written and verbal.
- Demonstrated organizational skills.
- Demonstrated self management and motivation.
- Strong problem solving skills.
- Strong interpersonal skills/team player.
- Positive and professional approach.
- Detail oriented
- Prioritization
- Flexibility

Job Description: Scientist/Senior Scientist, Formulation Development

Contribute to projects relating to the development of different dosage forms of small molecules. Responsibilities will include developing products from preformulation research through technology transfer to manufacturing.

Major Activities:

1. Plan and perform scientific experiments under supervision from laboratory scale to pilot scale using manufacturing equipment such as: High shear granulation, fluid bed drying, coating, encapsulation, compression roller compaction, and melt extrusion,. Experience in formulation including scientific knowledge of formulations, physico-chemical and biopharmaceutical principles underlying pharmaceutical dosage forms.
2. Plan, perform and contribute to project related scientific/technical activities with guidance (e.g., interpret and report results, generate and evaluate data, draw relevant conclusions).
3. Collaborate with team members (formulators, analytical chemists, and manufacturing technicians) to meet timelines for drug product delivery and assist in working out investigation plans to related to manufacturing investigations as required.
4. Interact/collaborate with other groups/functions to facilitate transfer of knowledge and deliveries of drug product.
5. Follow company policies and conduct work according to appropriate Frontage SOPs and comply with cGMPs.
6. Ability to motivate and work within a team environment.
7. Participate in departmental project teams/meetings.

Requirements:

Desirable: MS/PhD in Pharmaceutical Science or related fields

Languages: Chinese and English (oral and written)

Locations: Pennsylvania or China

Experience/Professional requirement:

1. Minimum of 2 to 3 (Scientist) or 4 to 6 (Senior Scientist) successful years of experience in the relevant position. Fresh graduates also may be considered (Associate Scientist).
2. Awareness/proven experience for safe handling of chemicals, potentially dangerous materials and equipment.
3. Good scientific or technical knowledge in Pharmaceutical dosage forms
4. Adequate knowledge of software and computer tools.

Job Openings in Analytical Services**Analytical Chemist/Scientist - Job Code: AS09-1****Responsibilities:**

1. Performs HPLC/GC/IC/Dissolution method development and validation, and a variety of analytical tasks to support product development. Ensures agreed timelines.
2. Prepares relevant documentations as required.
3. Complies with applicable current GMP and GLP regulatory requirements and established company SOPs/policies while carrying out assigned projects

Qualifications:

- Level depending on education and experience. B.Sc., M.Sc., or Ph.D. with 1-3 years of hands-on HPLC/GC/IC/Dissolution experience in pharmaceutical analysis
- Highly motivated work ethic; Capable of juggling multiple tasks
- Excellent oral and written communications skills
- Industrial experience, including CRO experience is a plus

Group Leader - Job Code: AS09-2**Responsibilities:**

1. Manages the assigned analytical projects to support product development. Provides updates, resolves any unexpected issues, and ensures agreed timelines.

2. Prepares and/or reviews analytical test method, method validation protocol, method validation report, test protocols, test reports, COAs, stability protocol, stability reports, deviations/variances, Out-of-Specification (OOS) investigation reports and SOP's.
3. Evaluates and resolves analytical and instrumental issues.
4. Supervise a team of junior chemists. Provides technical guidance to lab staff and trains staff on new instruments and technologies.

Qualifications:

- Ph.D. in Analytical Chemistry or related discipline with a minimum of three years relevant experience in pharmaceutical or related industry
- Excellent oral and written communications skills
- Capable of setting priorities based on a fast-paced, changing environment
- Independent decision-making required to carry out day-to-day functions
- CRO experience is a plus

QC Reviewer - Job Code: AS09-3

Responsibilities:

Perform fast and accurate QC Review of notebook and data packages. Work with chemists, report writer and QA to ensure agreed timelines.

Qualifications:

- B.Sc.or M.Sc., with 3-5 years of relevant experience in pharmaceutical analysis
- Highly motivated work ethic; Detail-oriented professional; Capable of juggling multiple tasks

Please email your resume and salary requirement to dwang@frontagelab.com



About VP Discovery

VP Discovery (formerly Tripos Discovery Research) is recognized as a world class drug discovery service company and with 200,000 sf. Lab space. It has made notable achievements in the field of medicinal, synthetic and computational chemistry, and provided integrated drug discovery services to its clients. Now, as a member of the Venturepharm Group, VP Discovery can also provide a full range of drug discovery and development services from concept to clinic.

In addition to its state-of-the-art facilities in CMC China, VP Discovery can now draw on the resources from a global laboratories net work. The integration of capabilities from Venturepharm provides clients with a fully integrated offering from target discovery to IND enabling studies.

VP Discovery's aim is to become a preferred partner to biotechnological and pharmaceutical organizations which require high quality drug discovery capabilities to complement their internal resources. It endeavors to provide industry leading technology, professional project management and the expertise in target areas as a key advisory resource for clients.

Job Description for CSO

Work Location: CMC Taizhou China

Responsibilities:

- Provide strategic, managerial, and scientific leadership in the areas of chemical synthesis, etc.
- Participate as an active member of the Company Senior Management Team.
- Be responsible for strategy and implementation of activities, and is ultimately responsible for the quality of the work and its interpretation.
- Be responsible for coordination of functional area responsibilities in the context of matrix project team environment.

Requirements:

- Ph.D. or advanced degree in chemistry or pharmaceutical related sciences.
- More than 10 years experience in drug development industry.
- Must have an outstanding record of successful research, including publications in peer-reviewed journals.
- Demonstrated ability to guide groups through corporate change and growth.
- Interactive and collaborative approach; expert influence and conflict resolution skills are a must.
- The successful candidate must have a strategic orientation, while also ensuring that all tactical details are managed efficiently and effectively.
- Process working knowledge of international requirements of permits, logistics, and legal requirement of non-clinical testing.

Job Description for Chemical Director

Work Location: CMC Taizhou

Responsibilities:

This position will be responsible for managing Chemical synthesis programs in VP Discovery China located in Taizhou China. Key activities include project assessment, resource allocation, and recruiting, professional development for employees, comprehensive project updates, and exceeding customer expectations.

Requirements:

- Ph.D. in Chemistry and a strong scientific track record
- 5-10 years of relevant industrial experience, US experience preferable
- Successful track record in chemical synthesis while operating within aggressive timeline
- Comprehensive understanding of the pharmaceutical R&D process

- Strategic thinker with the ability to manage a fast growing business
- Flexible and innovative problem solver

Director of Business Development

Responsibilities:

- Execute all the business development activities and action plans;
 - In charge of business development activities.;
 - Establish and maintain positive contacts and working relations with existing customers ;
 - Identify potential customers and new market needs;
 - Maintain close contact with all departments in the company to ensure common awareness of company objectives;
1. Serve as liaison with all departments in China and overseas customers to achieve balance between the needs and the services produced;
- Generate proposals;
 - Provide necessary training to subordinates.

Qualifications:

- Advanced educational degree;
- Minimum 6 years of working experience in the pharmaceutical or healthcare industry in MNC ;
- Experience in chemical field is required; sales experience in chemical research field is preferred;
- With at least 2 years supervision experience;
- Demonstrated successful leadership skills and supervisory capabilities;
- Bilingual in English and Chinese;
- Be able to travel;
- Familiar with operating computer especially Microsoft office software (Excel, Word, PowerPoint, etc.)
- Strong communication ability;
- Able to work independently.



Opening positions of Shanghai ChemPartner

Shanghai ChemPartner is a leading service provider in China, focusing on customer synthesis, medchem, biology, chemical process development, and manufacturing. There are 1,600+ chemists in the company located in Zhangjiang Hi-Tech Park. With strong financial performance and healthy investment, the company has embraced its fast growth in recent years. To keep up with the growing demands for R&D outsourcing, we are looking for experienced candidates who are interested in joining us.

Biology

VP-Biology

Qualifications:

Ph.D. or equivalent degree in biochemistry, cell biology, or pharmacology with more than 3 years of drug discovery research experience in biotech or pharmaceutical industry. Expertise in developing various enzymatic, receptor-based, and cell-based assays, pathway mapping, and cell signaling characterization is preferred. Familiarity with assay technologies and compound library screening is desirable. Good organizational, communication and interpersonal skills, and has demonstrated achievements with publications. Understanding of drug discovery and development process and procedures, experience in research collaborations, and supervisory roles in the past are added qualifications for this position.

Principle Research Scientist-Cancer Pharmacology

Qualifications:

PhD degree, majoring in life science, biomedicine, cell biology or pharmacology and other related disciplines. Able to design, process experimental data and statistics independently. Strong communication and coordination capacity and able to work in a collaborative environment. Can withstand the pressure of work with a strong sense of responsibility

Principle Research Scientist-Cell biology leader

Qualifications:

PhD Degree in biomedical science, cell biology, pharmacology or related discipline. Hands-on experience in animal models and cell culture are essential with experience in cancer research. Have experience in experimental design, animal surgery, data interpretation and statistical analysis. A strong work ethic, excellent oral and written communication skills are essential. Understand of drug discovery and development process is desired.

Principle Research Scientist-QB leader

Qualifications:

Familiar with drug discovery process and related technologies and have strong background in Biochemistry cell biology. Over five-year work experience at drug screening. Desired. Skilled at establishing and problem solving cell based screening methods.

Project Management (Biology)

Qualifications:

Ph. D degree with pharmacy or other related background. Be able to operate analytical equipments skillfully, and to set up biological analysis experimental methods independently. Be able to manage biology analysis business, with related at least 5 years experience. People with the experience of biology analysis business in abroad are preferable.

Chemistry

Research Fellow-Process Analytical Development

Qualifications:

Hands-on method development experience and in-depth knowledge of chromatographic techniques such as HPLC, LC-MS, GC, GC-MS, chiral separations, and chemical and structural characterizations. Education in analytical chemistry, organic chemistry, or related disciplines. Have a degree of Ph.D. with 5 – 10 years, or M.S. with 15+ years of technical and managerial experience in pharmaceutical industry. Be responsible for departmental performance and individual performance evaluations. Be familiar with overall pharmaceutical development process, cGMP and regulatory guidelines.

Research Fellow-Preformulation Development

Qualifications:

Hands-on experience and in-depth knowledge are essential on thermal analysis, salt and polymorph screening, solubility, hygroscopicity, stress study, excipient compatibility, and overall solid state characterizations using TGA, DSC, microscopy, XRD, and particle size measurement. Education in pharmaceutical sciences, physical chemistry, or analytical chemistry. Have a degree of Ph.D. with 5 – 10 years, or M.S. with 15+ years of technical and managerial experience in pharmaceutical industry. Be responsible for departmental performance and individual performance evaluations. Be familiar with overall pharmaceutical development process, cGMP and regulatory guidelines.

Research Fellow-cGMP Kilo Lab

Qualifications:

Have very strong knowledge of organic synthesis. A Ph.D. in Organic Chemistry with at least 5 years of industrial experience in process chemistry area. Have a record of accomplishment in chemistry and significant leadership experience, and should have good communication skills.

Research Fellow-Medicinal Chemistry

Qualifications:

PhD in organic or medicinal chemistry field with 10 years of technical and managerial experience in pharmaceutical industry. Innovative problem solver, dedicated and dependable. An outstanding accomplishments in medicinal chemistry with GPCR or kinase, protease or ion channel targets are desired.

Principle Research Scientist- Medicinal Chemistry

Qualifications:

PhD in organic chemistry or related field with 5-8 years of technical and managerial experience in pharmaceutical industry. Innovative problem solver, dedicated and dependable. An outstanding accomplishments in medicinal chemistry with GPCR or kinase, protease or ion channel targets are desired.

Principle Research Scientist -Nucleoside Chemist

Qualifications:

PhD Degree and majoring in Organic Chemistry or Medicinal Chemistry. At least 5 years working experience in pharmaceutical company. Be familiar with Synthesis Chemistry and Nucleoside Chemistry. Ambitious, responsible, cooperative, hard working and innovative having the ability to solve problem alone.

For more information about us, please to to: www.chempartner.com or www.shangpharma.com .

Discover your future with us by sending your CV to recruitment@chempartner.cn.



BioDuro Job Openings:

Director of Computational Chemistry

We are seeking an outstanding informatics leader with the right balance of technical expertise and business acumen to design, develop and implement an informatics platform to support an emerging drug discovery company.

Responsibilities:

- Direct the design, development, implementation, and maintenance of informatics solutions and overall research computing capabilities which are directly aligned with the priorities of the research and development organization.
- Oversee and manage all IT infrastructure including systems management, end user computing, storage management, and network management.
- Conceive and develop novel informatics tools and exploit emerging information technologies as required to directly support research and development goals.
- Manage access to public and proprietary third-party information/databases.
- Build and manage a staff of professionals who work collaboratively with research project teams to ensure that scientists get the information they need, when they need it while also collecting archiving data and information as a corporate asset.

Background and Experience:

- Ph.D. in Computational Chemistry, Computer Science or related life sciences field.
- Minimally eight (8) years of industry experience in supporting pharmaceutical drug discovery/development.
- Minimally three (3) years of supervisory experience.
- Significant experience and a proven track record of designing software systems to support research and development.
- Expertise in software engineering, database design, and database management
- Expertise in scientific information management.
- Outstanding oral and written communication skills, as well as polished and persuasive presentation skills.
- Ability to work on abstract problems across all functional areas of the company as part of interdisciplinary team.
- Established track record of building and leading high performance teams of technical talented scientists producing high quality work on time and within budget.
- Understanding of biology, chemistry, pharmacology or clinical sciences required to work credibly with discovery scientists.
- A demonstrated drive to apply technical knowledge to develop systems and processes in a timely manner.
- Ability to effectively align individual staff interests with work assignments.
- Recognizes individual and team contributions and aligns rewards to performance.

Director of Medicinal Chemistry

This position will be responsible for managing medicinal chemistry programs in BioDuro's R&D center located in Beijing China. Key activities include project assessment, resource allocation, and recruiting, professional development for employees, comprehensive project updates, and exceeding customer expectations.

Requirements:

- Ph.D in synthetic organic chemistry or medicinal chemistry and a strong scientific track record
- 8-12 years of drug discovery experience, US/EU experience preferred
- Successful track record in medicinal chemistry while operating within aggressive timelines
- Deep understanding of the pharmaceutical R&D process
- Strategic thinker with the ability to manage a fast growing business
- Flexible and innovative problem solver

Group Leader

This position will be responsible for managing a high performance chemistry team in BioDuro's R&D center located in Beijing China. Key activities include synthetic chemistry design and development, project management, performance evaluation, project status updates, and exceeding customer expectations.

Requirements:

- Ph.D. in synthetic organic chemistry or medicinal chemistry with a strong scientific track record
- 2-5 years of relevant industrial experience
- Successful track record in synthetic and/or medicinal chemistry while operating within aggressive timelines
- Understanding of the pharmaceutical R&D process
- Hands-on operational manager
- Flexible and innovative problem solver

Scientist/Senior Scientist in Electrophysiology

The successful applicant will join our research efforts to develop and understand the electrophysiological actions of ion channel inhibitors. This scientist will screen compounds against heterologously expressed or native ion channel targets (e.g. hERG) from excitable cells (e.g., cardiac, HEK293) using patch-clamp techniques. In addition to patch-clamp electrophysiology assays and research, duties may include maintaining cell cultures, method development, data analysis and presentation, and writing of technical reports and original manuscripts.

Qualifications:

This position requires a minimum of a Master's degree with in-depth electrophysiology experience, or a Ph.D. in physiology, biophysics or pharmacology with ion channel research experience. Prior job experience in a biotech or pharmaceutical company is beneficial but not required. The successful applicant should have first-hand experience in patch-clamp methodology. Experience in cellular and molecular biology is a plus, but not a pre-requisite. Knowledge of common laboratory instruments and general lab procedures, experience with primary cell culture, as well as knowledge of software used for electrophysiological experiments is required. Experience with automated patch-clamp system is a plus. The successful candidate will demonstrate the ability to organize and present data, have strong written and oral communication skills, and have a history of working well in a team-oriented environment.

Scientist

This position will be responsible for contributing to projects in biology, as a member of the high performance biology team in BioDuro's R&D center in Beijing China. Key activities include: Cloning various genes and constructing mammalian expression vectors; Establishing stable expression cell lines, Developing cell functional assays, and Preparing comprehensive scientific documentations.

Job Requirements:

- Ph.D./MD in biology or pharmacology
- 0-5 years of relevant industry experience
- Molecular biology experience required: genetic database querying; sequence analysis; gene cloning, and expression vector engineering
- Excellent mammalian cell culture skill required, mammalian expression experience (e.g. GPCR, etc) preferred
- Experience in stable cell line generation and characterization preferred.
- Cell functional assay, FACS (flow cytometry), and fluorescent microscopy experience preferred.
- Familiarity with data analysis software preferred
- Energetic, flexible and innovative, able to trouble shoot and work in a fast-paced environment.
- Excellent English reading and writing ability

[Apply now for this position.](#)

Director of Pharmacology, China

This position will be located in Beijing, China and will be responsible for developing and supporting GLP quality pharmacology research capabilities. The main focus of this function is to manage a highly motivated team of five to ten Ph.D., Masters or B.Sc. level pharmacologists, engaged in providing pharmacological study support for all of BioDuro and/or corporate projects. Key activities will include the construction and management of the centralized PK-PD laboratory capabilities including animal facility, and the design and execution of dose ranging and ADME studies. This function will work with colleagues in the US to evaluate resource needs, estimate costs, and design, implement and deliver results for customer projects. This will also entail regulatory documentation and compliance.

Requirements:

- Ph.D./MD in pharmacology
- 10-15 years of relevant industry experience
- Deep understanding of PK, PD, and ADME areas including experimental design, analysis, and regulatory compliance
- Strategic thinker able to build & manage a fast growing business
- The candidate should be: high energy, team oriented, and possess the ability to work well under pressure
- Must also be highly organized and thorough, independently motivated and have excellent interpersonal and communication skills.

[Apply now for this position](#)

Director of Drug Safety Evaluation

This position will be located in Beijing, China and will be responsible for developing and supporting GLP quality drug safety evaluation services. The main focus of this function is to manage a highly motivated team of five to ten Ph.D., Masters or B.Sc. level toxicologists, pathologists and technicians, engaged in providing drug safety evaluation study support for all of BioDuro and/or corporate projects. Key activities will include the design and execution of GLP Drug Safety Evaluation and pathology studies and coordination with the animal facility. Regulatory documentation and filing will also be part of this individual's responsibilities.

Requirements:

- Ph.D./DVM
- 5-15 years of relevant industry experience
- Deep understanding of TOX/Drug Safety areas including design, analysis, and regulatory compliance
- Comprehensive understanding of the pharmaceutical R&D process
- The candidate should be: high energy, team oriented, and possess the ability to work well under pressure
- Must also be highly organized and thorough, independently motivated and have excellent interpersonal and communication skills.
- Able to communicate effectively in written and oral forms.

[Apply now for this position](#)

Director of DMPK

This position will be located in Beijing, China and will be responsible for developing and managing advanced DMPK research capabilities. The main focus of this function is to manage a highly motivated team of over 20 Ph.D., Masters or B.Sc. level DMPK scientists, engaged in providing drug metabolism and pharmacokinetics study support for all of BioDuro integrated projects, as well as external DMPK service. This position will manage in-vitro ADME, in-vivo PK and bio-analytical teams PK. Key activities will include providing scientific leadership to the department, designing DMPK studies, and providing data analysis and guidance to medicinal chemistry team. The responsibilities also include planning and executing future expansion, developing and establishing new and advanced DMPK capabilities, providing training to DMPK scientists.

Requirements:

- Ph.D. in pharmacology or in Chemistry
- Over 8 years of relevant industry experience
- Must be very experienced in in-vitro ADME and in-vivo PK and is able to interpret experiment data, to troubleshoot problems and to provide analysis, feedback and guidance to medicinal chemistry projects
- Must have extensive experience in working in multiple medicinal chemistry programs
- Must demonstrate scientific excellence in DMPK
- Strategic thinker able to build & manage a fast growing business
- The candidate should be: high energy, team oriented, and possess the ability to work well under pressure
- Must also be highly organized and thorough, independently motivated and have excellent interpersonal and communication skills

Open Position at Food and Drug Administration (FDA)

Center for Drug Evaluation and Research, Office of Clinical Pharmacology New Reviewer Position Description (DRAFT) Clinical Pharmacology Safety Reviewer

Advancing Safety Science in Clinical Pharmacology in the 21st Century

Background: Office Need

CDER has taken heed of the calls for a stronger emphasis on drug safety. The Sentinel initiative, various risk management plans and numerous post-marketing requirements represent some of the initiatives related to premarketing safety assessment and post-marketing pharmacovigilance.

One of the primary objectives of clinical pharmacology reviews is to inform patient care. This requires a commitment from clinical pharmacologists to understand the interactive relationship between drug dosing and clinical outcomes at the interface between the genetic make-up of individual patients, the environment, their disease and pharmacotherapy. These factors collectively contribute to the complex balance between the benefit (effectiveness) and safety risks (harm) of pharmacotherapy

Biomarkers represent a unifying theme to explain sufficiently – if not completely – the relationship between drug administration and clinical safety phenotypes. For example, there are several high-profile examples where biomarkers might have been particularly helpful to detect early signs of vascular toxicity or drug-induced risk of thrombosis from the administration of torcetrapib, rosiglitazone and certain COX-2 inhibitors

A 21st century view of biomarkers and drug safety builds on a strong mechanistic foundation provided by early observations in clinical pharmacology studies which can be used to probe the mechanisms for adverse drug reactions in later randomized controlled trials. This “translational” approach can also be used to establish hypothesis and gaps that can be the subject of post-marketing commitments and advanced regulatory research.

Organizational Structure

The proposal is for having one clinical pharmacology safety reviewer in each division who is responsible for covering the respective therapeutic areas within that division. He or she will report directly to the Division Director and work in concert with the Deputy Director and Team Leaders of the Division.

Overall coordination of the OCP safety program will be the responsibility of someone in the immediate office.

Duties and Responsibilities

The Clinical Pharmacology Safety Reviewer is responsible for innovation and forward thinking about drug safety as illustrated by the following responsibilities

- To develop a scientific, biomarker-based framework for evaluating adverse drug reactions in individual patients and patient subgroups as a complement to traditional population-based clinical pharmacology reviews
- Review safety signals and their time course as detected in the RCT in phase 3 of drug development in order to identify patterns of potential causes of adverse drug reactions
- To mechanistically link drug dosing and clinical safety outcomes, and map the biomarkers of the clinical safety phenotype back to what is known about the clinical pharmacology (e.g., susceptibility factors affecting PK, PD and D/R or PK/PD relationships) of the drug to elucidate what might possible predispose individuals patients to adverse events
- To ensure as positive, if not more positive, benefit-risk profile in patient subsets not enrolled in registration trials but who are eligible to received a drug for the approved indication
- To look for validated and potentially new molecular signatures and biomarkers derived from genomics that may improve our understanding of the safety of pharmacotherapy as it applies to individual patients and patient subsets
- To apply quantitative methodologies from pharmacometrics to integrate and analyze relationships between drug dosing and clinical safety outcomes to define the probability or likelihood of adverse drug reactions
- Evaluate comparative drug safety (e.g., between members of the same pharmacological class) and what clinical pharmacology factors distinguish the safety of one member from another
- To apply knowledge gained from the mechanism of adverse drug events to identify predictive safety biomarkers for future reviews that might be used across multiple therapeutic areas – not drug specific -- to prevent or better understand drug safety
- To propose research projects whose results would bring value (defined as quality/cost) to the drug safety
- To apply sophisticated data-mining tools (e.g., Biovista) to permit analysis of adverse reactions across therapeutic areas for better prediction of general risk factors for new and previously approved drugs
- Identify potential premarketing safety signals that might warrant a more targeted plan for pharmacovigilance in the post-marketing period
- Use prior knowledge of clinical safety phenotypes and clinical pharmacology to identify testable hypothesis about the causes of adverse drug reactions which can be studied mechanistically as post-marketing commitments
- To track and review post-marketing requirements in clinical pharmacology, and to oversee consistency in requesting and designing post-marketing clinical pharmacology studies across therapeutic areas
- Maintain a database of known relationships between clinical pharmacology risk factors and adverse drug reactions
- To monitor post-marketing safety signals that represent risk in the real world for additional insights into the mechanistic basis of adverse drug reactions; look for trends in issues brought to the CDER Drug Safety Oversight Board and CDER Regulatory Briefings
- Assess the impact of the OCP safety program and document actual successes

- Prioritize safety reviews based on criteria such as the likelihood of the adverse event being mechanistic (i.e., expected from the target and off-target pharmacological effects) vs idiosyncratic (confounded by multiple factors), known drug class effect or not, severity and frequency of the event, and the potential for risk mitigating strategies
- To conduct a series of external focus groups to assess the quality, usability and consistency of information in product labels which is based on the clinical pharmacology of the drug

Preferred Candidate Expertise and Experience

The clinical pharmacology safety reviewer will have an advanced degree, such as a Pharm.D., R.N., M.D., and/or Ph.D. degree.

The ideal candidate will:

- Have 5 years or more experience in clinical practice, i.e., patient care, and a broad understanding of clinical pharmacology, mechanisms of adverse drug reactions and ways to optimize or individualize patient care
- Have leadership and/or managerial experience building a scientific and/or clinical program which requires relationship-building and coalitions with multiple disciplines
- Have critical thinking skills and evidence of evaluating clinical trials to identify causative factors in at-risk patients
- Proven track record of scientific accomplishments including invited presentations and peer-reviewed publications
- Excellent verbal and written communication skills with proven ability to influence and bring added value to scientific and clinical decision-making
- Be able to represent and advocate clinical pharmacology safety science well within FDA and external in the scientific/clinical communities

Contact Person for Further Information

Dr. Mimi Phan
Senior Regulatory Specialist
mimi.phan@fda.hhs.gov
301-796-2213

Organizing Committee

Li Yan (Co-Chair)

Jianguo An
Chang Bai
Zhibiao Fu
Jian He
Ming He
Tony Wei-hsiu Ho
Laura G. Hong
Weihong Hsing
Tao Jiang
Lee Kang
Wensheng Lang
Jian Li
Jiangfan Li
Kai Li
Li Li
Bo Liang
Yin Liang
Frank Liu
Peter Luo

Tsang-Bin Tzeng (Co-Chair)

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Li Shi
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Hancheng Zhang
Yun Zhang
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