



Letter from the President

Dear AACT members,

The AACT board was very pleased that the 2012 AACT reception in San Francisco was a success. It was great seeing our members network and make new friends over the Banquet meal at the Canton Restaurant. I particularly enjoyed hearing all the lively conversations. Many thanks to our Sponsors for their support in feeding the 260 attendees. We unfortunately were not able to find a reasonably price restaurant near the San Antonio Convention Center that could accommodate our large group, so the 2013 AACT reception will be held in an SOT meeting venue. We hope in 2014 we can return to the restaurant format in Phoenix, AZ. The 2013 AACT events will again be the Distinguished Toxicologist Lectureship and Reception on Monday, March 11 starting about 5 pm and a Career Development Workshop for our young toxicologists (Date and Time TBD).

I'm also very happy to announce that AACT has achieved our goal of having **OVER 200 MEMBERS**. We are also making progress expanding our global footprint; in addition to members in the U.S., we have members in China (15), Canada (5), Netherlands (2), Germany (1), Sweden (1), Switzerland (1), and the UK (1). With ~216 members, we are tied with Association of Scientists of Indian Origin (ASIO) for second, with Women in Toxicology (WIT) being the largest (~600 members). With the challenging toxicology job market in the U.S., thoughts of working in China likely has crossed some of your minds. Therefore, we reached out to a couple of members to share their perspectives on the current conditions of drug development. Both Mingli Chen and James Yan received their graduate degree, worked in the U.S. for several years before returning to work in pharmaceutical/CRO industry in China. Hopefully with more returnees, the AACT network will be larger in China and help those of you transitioning there.

Lastly, I'd like to recognize our outgoing Board Members Jiaqin (Jack) Yao (Treasurer), Tao Wang (Councilor), Yi Yang (Secretary), and Xun Zhang (Postdoc Rep), all of whom worked very hard for the past two years to support AACT's

growing efforts. I'd also like to welcome aboard the new Board members Ching-Hung (Gene) Hsu (Councilor), Weimin Gao (Councilor), and Xi Yang (Postdoc Rep) have already jumped in to help the continuing board members, Edward Chow (President-Elect), Lu Cai (Treasurer), Tim Lam (Secretary), and Weimin Chen (Student Rep) with the AACT activities for 2013. We have a lot of work ahead of us so if you would like to help out too, please contact a board member or one of the committee chairs listed on Page 2.

Thank you all so much for being part of the AACT Membership! Please encourage your colleagues to join AACT, either as an SOT member or as a non-SOT member (more details on Page 2).

All the Best,

Diana J. Auyeung-Kim
AACT President

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**See you in 2013
@ San Antonio,
TX!**

Distinguished Chinese
Toxicology Lecture
(5 pm March 11, 2013)

AACT Annual Business
Meeting and Reception
(6 pm, March 11, 2013)

AACT/KTAA Career
Development Workshop
(time and place to be
determined)





Left to right: Edward Chow, Weimin Gao, Diana J. Auyeung-Kim, Xi Yang, Lu Cai, Jia Sheng Wang, Weimin Chen, Ching-Hung (Gene) Hsu

AACT 2012-2013 Officers

President: Diana J. Auyeung-Kim

President – Elect: Edward Chow

Secretary: Tim Lam

Treasurer: Lu Cai

Past Present: Jia Sheng Wang

Councilors: Weimin Gao and Ching-Hung (Gene) Hsu

Postdoctoral Representative:

Xi Yang

Student Representative:

Weimin Chen

Welcome to Join AACT

AACT Committees

If you are interested in becoming a volunteer or joining any of the committees and working for AACT, please contact the chairs:

- Award Committee: Edward Chow (chow_edward@allergan.com)
- Finance Committee: Ching-Hung (Gene) Hsu (chhsu@ncdser.com)
- Membership Committee: Weimin Gao (weimin.gao@tiehh.ttu.edu)
- Program Committee: Diana Auyeung-Kim (taedi0611@gmail.com)
- Nominating/ Election Committee: Jia-Sheng Wang (jswang@uga.edu)

- To join AACT and SOT, go to: <http://www.toxicology.org/ms/join.asp>
- Already an SOT member and need to add AACT go to: <https://www.aim-hq.com/netFORUMSOT/eweb/DynamicPage.aspx?Site=SOT&webcode=AIMOutstandingDuesNew>
- \$15 per annum add-on to your SOT dues
- Free for Postdoctoral and Student SOT members (first SIG only) or \$15 for each additional.
- For non-SOT members, you can still become an AACT member, but will receive limited membership privileges. Application form is available by contacting Lu Cai (lu.cai@louisville.edu) or Diana Auyeung-Kim (taedi0611@gmail.com).

Many thanks to our 2012 AACT Meeting Sponsors



Congratulations to 2012 SOT Meeting Award Recipients

Distinguished Chinese Toxicology Lectureship Award



Dr. James Kang, DVM, PhD, FATS
Professor and Distinguished University Scholar
University Of Louisville

2012 Jean Lu Student Scholarship Award Winner AACT - Charles River Best Abstract Award 1st place



Tongde Wu, Graduate student
University of Arizona

AACT- Charles River Best Abstracts Award Winners



Weimin Chen, Graduate student, 2nd Place
Michigan State University



Bin Sun, PhD, 3rd Place
The Hamner Institute for Health Sciences



2013 SOT Annual Meeting AACT Award Application Deadline

- AACT and Charles River Best Abstract Award **Dec 15, 2012**
- AACT Jean Lu Student Scholarship Award **Dec 15, 2012**

Please submit your applications or nominations to Dr. Edward Chow (chow_edward@allergan.com) before the deadline. Award guidelines and further information about each award are available on AACT website:

<http://www.toxicology.org/isot/sig/aact/criteria.asp>

Career Center

Working in China and Random Thoughts on China's Pharmaceutica

Mingli Chen, MD, MS, DABT
Vice President of Non-clinical Project Management
WuxiAppTec Co.,Ltd.



As more and more peoples are thinking about returning to China, I am hoping to give you a glimpse of how it is like to live and work in China as a returnee from my personal experience. It's also my intention to share some random thoughts on China's pharmaceutical R & D.

Personal experience working in China

August 2008, I was assigned as a scientific lead for a Joint Venture company based in Shanghai. Initially I was very reluctant to take the offer even though my husband had been working in a local company for almost a year. Working in China for a period of time is one thing which is probably desired by most of us including many of Westerners. However, moving back entire family is totally different. At that time, our son already started college and our daughter was at third grade at elementary school. So our decision of moving to China was relatively easy. But the truth is that it's never easy to make such move after living in the US for nearly two decades. We sold and got rid of almost everything and moved entire family but our college son to Shanghai.

There are more than a handful of well established international schools in shanghai, so we had little trouble finding a suitable school for our daughter. She got happy with her school and friends soon and we also quickly adjusted to become like the city life which is in fact our very first experience.

My work at JV company came a long way. I basically had to work long hours each every day supervising scientific activities, providing trainings, interacting with multiple departments within my parent company and most importantly spending countless time dealing with clients. I am proud to say that the JV was at the time among the first a few CROs within China that were capable of conducting GLP toxicology studies met FDA GLP requirements.

After two years working for the joint venture, the two companies decided to pursue separate business pathways. I was faced with a decision to either returning to the US working for my parent company or staying at the Chinese company which was buying the JV. At the time I was approached by several including prime Chinese global companies and I have left the JV and started working for my current company, Wuxi AppTech.

During the first a couple of years, we always thought that working and living in China was temporary and thought about returning to the US anytime much like the first few years we came to the US thought about returning to China. After about two years, we began to realize that we want to stay for longer. Our daughter complains once a while about living in China and wants to go back to the US for school, friends and life style. But mostly we all pretty much enjoying living in China for few reasons. First it is clear that we do not want to own a car, or to drive a car in China. Taxi and public transportation are convenient especially in Shanghai. It's a good feeling for not owning a car or house, and worry free. Secondly, among many other misc. benefits of living in China, food comes on the top. Even the kids have learned eating seafood, tofu, and all kinds of soups etc which will benefit their entire life. Furthermore, both kids have made solid progress in learning Chinese language, culture and history. This alone would make our China experience worthwhile.

Random thoughts on China's Pharmaceutical R & D

For the last several years, preclinical spending has decreased substantially from its peak. As a result, down-size, reorganization and lay off were witnessed among almost all large pharmaceutical companies, biotech companies as well as major CRO companies. However China operations continue to expand at least for most of top 20 global pharmaceutical companies. On the one hand, Chinese businesses are indeed growing; on the other hand, it's probably a strategic decision to position for a longer term perspective.

For China's local companies, over the last 5-10 years, there has been a drastic growth both in capacity for the existing CROs and number of the new CROs in the preclinical development. Most of expansions are due to the funding came from various governments (Central or local governments). Some of significant funds also came from private sources. There are more than 40 preclinical toxicology service organizations certified by SFDA. Even so most of major organizations were very busy thanks to numerous number of drug development programs carrying on by companies including traditional pharmaceutical companies, large number of startup companies and universities.

The pharmaceutical industry is a major component of biomedical industry which is considered as one of seven strategic new industries for the twelve five-year plan. The government alone is to spend over 40 billionRMB special funds between 2010 to 2015 to support new drug development. It is difficult to estimate a total amount of actual investment as it will be largely affected by local governments. For example, it was reported that Yunnan province alone to invest over 80 billion RMB to boost its biomedical industries during the year 2010 to 2015. As many of local governments have determined to place the biomedical industry as their priority of development, it is expected that the enormous amount of funding will be spent on drug development.

China has targeted to achieve total revenue of 3.7 trillion RMB at the year 2015 for its pharmaceutical industry. Besides revenue, China has determined to become a power house for drug development instead of drug production. This will place China as a world No 2 position in pharmaceutical industry.

Besides enormous funding coming from the government, Chinese pharmaceutical companies have accelerated their R & D efforts for new drug development. After a few decades of accumulation and growth, many Chinese pharmaceutical companies are now cash rich although R & D spending remains low (low to mid single digit percentage of the revenue). Universities have historically played a major role in China's pharmaceutical R & D. A close collaboration between the universities and biopharma companies are essential for increasing productivity from bench to medicine.

As many of rich peoples are cashing out from a decade-long housing booming or others, some of them have invested in the pharmaceutical industry to take advantage of benefits offered by local governments ranging from free land, free rental, matching-fund as well as tax benefits. So if you ever dream about starting up a business adventure, it is still a good time to do so within China. Besides the foreseeable growth potential in general, you will receive enormous supports and benefits from various governments. Of course the benefits and supports can't be the primary reason of starting up a business in China.

Global pharmaceutical industry has gone through a nearly decade-long restructure mainly due to stagnation of the businesses on the wake of struggling in developing new drug pipeline as well as the time and costs involved in drug development. The down-size and reorganization have been accelerated during last several years of the global economic recession. However almost all those global companies continue to expand their China operations. It is clear that the global pharmaceutical companies have determined to deepen their footprint in China.

Overall, it is a good and in fact rather exciting period of time working in China. Although there remain so many rather negative things like pricy almost everything, corruptions everywhere, lost of core value and trust, and crowd and less pleasant environments in most places. Like many others, I could foresee crisis coming from many directions. But I like to believe that China will somehow eventually find ways through all those bumpy roads. Pharmaceutical industry is well positioned to grow for many years to come as China continues its development momentum. China is destined to play a major role in global drug development and production from now and on.

Job Websites in China

中华英才网:www.chinahr.com

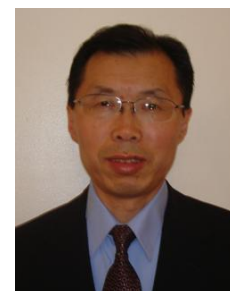
智联招聘:www.zhaopin.com

前程无忧: www.51job.com

Career Center

Preclinical Drug Safety Evaluation in China

James S Yan, PhD, MD, DABT
Covance Pharmaceutical R&D (Shanghai) Ltd.



In the past decade, new drug research and development (R&D) in China has been dramatically developed and improved which are driven by the sustained fast growth of China's economy; the interests of multinational pharmaceutical companies in the emerging market of China; and the supports from Chinese government to build up the innovation-driven drug development powerhouse. With the initiation and development of new drug R&D and the requirements of preclinical studies, the drug preclinical development including drug safety evaluation in China has also gained an extraordinary growth especially after the publication of GLP standard in 2003 and the series of the guidelines for new drug development since 2005 by China SFDA. Per the requirements, prior to the first in human study in China, all new drug candidates have to be evaluated their safety in animals under the GLP compliance in a GLP lab which certified by the SFDA. To date, there are about 50 labs received the GLP certificate from the SFDA. In China, all of the preclinical drug safety evaluation studies are conducted in these GLP certified labs.

To give our AACT members some ideas of understanding the preclinical drug safety evaluation in China, but also, most importantly, to help those who are interested to pursue their career development in the preclinical drug safety evaluation field in China, I will briefly introduce the current capabilities and limitations of the drug China GLP labs and the challenges which they are facing.

The GLP certified labs in China can be classified as three different types: government fund drug safety evaluation centers, private-owned the CROs, and multinational preclinical CROs. Between these labs, the service capability and quality as well as the capacity of these labs are very varies. In last decade especially last five years, several of these GLP certified labs in China have improved their capabilities and operation system significantly through the practices. Some of the studies conducted in these labs have been submitted to and accepted by the US FDA as part of the IND package. Few of these labs also have been inspected by OECD members and received the OECD GLP certificates from some OECD countries. All these indicated that the preclinical drug safety evaluation, in some areas such as the short term general toxicology studies is nearly mature in these labs. Given the short history and time period, this is a significant achievement in China GLP and preclinical drug safety evaluation. However, in the meantime, there are still many limitations and challenges need to be improved and overcome.

Personnel and expertise: Due to the short history of the new drug R&D in China, most of people in the preclinical drug safety evaluation field have limited skills and working experiences in drug R&D. This is really a bottle neck. It is very critical in the preclinical CROs as almost all of Chinese pharmaceutical companies as well as more and more pharmaceutical and biotech companies outside of China are expecting to receive not only the services but also the ideas. Therefore, the preclinical CROs will need more experienced personals such as Study Director or/and functional manager who understand all the new drug development requirements in different regions and can use not only the hands but also brain to work with the clients. Some of the specialized expertise, such as experts in DART, safety pharmacology, and carcinogenicity study as well as toxicological pathologist and DVM are also needed to set up or improve the service capabilities in those areas.

Limited experiences in long term general toxicity studies: In China new drug R&D, the majority of the drug candidates are still in the early development stage. The preclinical drug safety assessments of these candidates are mainly short term general toxicity studies to support phase I clinical trials or first in human studies. The long term or chronic toxicity studies are not required at this stage. Therefore, as mentioned above, the service capabilities and qualities of the short term general toxicology studies are nearly mature in several top China preclinical CROs. But, they have not received many opportunities to conduct the long term or chronic toxicity studies and have limited experiences in these studies.

Limited service capability in special toxicity studies: Due to lack of the special expertise in DART especially in non human primate (NHP) and in Safety Pharmacology (such as telemetry), the capabilities of these specialized studies are still very limited in China.

Lack of the background information and expertise to support the carcinogenicity study: In China, the SFDA issued the carcinogenicity guideline last year, but there is no lab has done any carcinogenicity study yet. Some of the labs are conducting validation studies to check any impacts of animal environment (such as animal quality, diet/bedding, and drinking water, etc) and to collect some background information. Given more special expertise will be needed for conducting and evaluating the carcinogenicity study, this may take longer time to set up in China.

Operation and documentations: Only few preclinical CROs are using the electronic data capture system to collect the data during the study conduction. But most of them are still using the paper documentations with the hand writing. Currently, in order to bring their operation and document managements to the next level, some of the top preclinical CROs in China start to evaluate the possibility of installing the electronic data management system.

In summary, the preclinical drug safety evaluation in China has been dramatically developed and improved during last ten years. The capability and quality of preclinical drug safety evaluation in some of the areas are nearly mature. However, in other areas, there are still limitations and challenges which need to be improved and overcome. For the forks who are working in China, they should work together very hard to overcome these challenges. For those who are interested to work in China, probably these challenges may become a great career development opportunity.

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(www.toxchange.org)



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- 3) In the Forum section, click on our Discussions headline.
- 4) Click on the "Subscribe" button on the right-hand side of the page.
- 5) Choose your discussion topic and begin posting, commenting, and browsing!



Many thanks for our outgoing Board Members Jiaqin (Jack) Yao (Treasurer, 2nd from right), Tao Wang (Councilor, 2nd from left), Yi Yang (Secretary, not pictured), and Xun Zhang (Postdoc Rep, 1st from right)!

AACT Upcoming Election (2013)

- Please nominate or run for position of President-Elect, Councilor, Student and Postdoc Reps. Nominations will be accepted by January 15, 2013.

Please visit our website at

<http://www.toxicology.org/isot/sig/aact/index.asp>