

## President's Message

It seemed like not a long time ago that we met in Baltimore. The unexpected snow is still in my memory. I was only reminded of how time flies when the board has started to prepare for the 2018 SOT Annual Meeting.

Despite the harsh weather, we had a high attendance rate in the AACT annual reception and the career development Workshop in March. We honored the selected distinguished toxicologist, postdoctoral and graduate student award recipients at the AACT reception. We invited 3 toxicologists who moved from America to China and achieved great success there to share their working and living experience, which drew great interest from the graduate students and postdocs.

In addition to the celebration of the achievements at the AACT annual reception, the elected new board presented our future working plans. Today, while writing this message to you, I am so glad to see that we have almost completed all activities we planned.

The AACT delegation's China trip for the 8th Chinese Society of Toxicology was enjoyable. We organized a very successful AACT session on safety evaluation of advanced therapies. AACT members, including Robert Li, Matt Liu, Ting Su, Qihong Huang, Yi Jin, and myself presented thoughtful views from regulatory, pharmaceutical companies, and CRO perspectives. In addition, Sherwin Yan, Pan Chen, and Zhibin Wang presented their work in other CSOT sessions. Presentations from our AACT members received high praise from all sides. In my presentation, I specifically introduced AACT to the audience and encouraged CSOT members to join AACT. On the last day of the CSOT meeting, I met Dr. Pingkun Zhou, the president of CSOT and discussed the potential future cooperation between AACT and CSOT. Dr. Zhou encourages AACT continue to organize scientific sessions in future CSOT meetings. I would like to see more AACT members apply for AACT delegations for next CSOT meeting in 2019.

After the CSOT meeting, I organized an AACT workshop at the Center for Drug Evaluation in China FDA (CFDA). The purpose of this workshop was to introduce CDE drug reviewers to how drug safety evaluation is conducted in Pharmaceutical companies in America. The speakers were Qihong, Matt, Robert, and Ting, and they introduced their companies briefly to CDE reviewers



## Event Board

### ***SOT 57th Annual Meeting and ToxExpo***

***—2018 March 11-15***

***Henry B. Gonzalez Center***

***San Antonio, TX, USA***



**徐增军 博士**

Dr. Z. Alex Xu, PhD, DABT

AACT Current President (2017 – 2018)  
中华人民共和国国家食品药品监督管理总局药品审评中心药理毒理首席科学家

before giving their scientific presentations. Both the speakers and CDE reviewers enjoyed the Q&A session very much. We plan to have more workshop and/or training sessions and more frequent communications between CDE and AACT in future.

On Nov 14th, AACT hosted its first SOT-wide webinar. This platform was created to provide opportunities for AACT members and other toxicologists of Chinese background to present their work and success. We invited Dr. Ying Huang from FDA/CBER to talk about the safety evaluation for gene therapy products. Gene therapy products became a very hot topic after FDA approved the first Car-T product from Novartis. This Webinar attracted over 100 people, many of which are AACT members. The second AACT webinar is on the way, and the board is screening possible topics and speakers. I encourage all AACT members who are interested to contact us.

We have promised to update our website to make it better, but this work is still ongoing. The board has had multiple discussions on how to improve our website.

I believe many of you have seen articles that introduced AACT activities on the SOT website. We submitted these articles to increase AACT visibility. AACT's presence has been well recognized within SOT. Lastly, I want to mention that although our fundraising has made good progress thanks to the diligent work from the board, I continue to encourage you and your company to support us financially. Your support is essential for our success.

I cannot finish this article without expressing my personal gratitude for our board members. Everybody is motivated by the chance to serve the AACT community, and cooperates with each other selflessly. I have to say, based on my experience, that I enjoy working on the AACT board, and I have learned a lot during the time I have served. I encourage whoever would like to serve the community to run for the open board positions.

*Z. Alex Xu*

*Current AACT President*

**2018 December**

With the support from SOT, AACT hosted its first SOT-wide webinar for Development and Safety Evaluation of Gene Therapy Products. Dr. Ying Huang gave a talk titled—

***“Preclinical Considerations for Gene Therapy Products: an FDA Perspective”***

She is responsible for the review of the preclinical evaluations for proof-of-concept and safety related to cell and gene therapies, and gene editing derived gene therapy products on oncology and non-oncology diseases. This webinar was a huge success, with more than 100 registrants and over half participates stayed longer for the active Q&A session (about 10 questions submitted to the speaker). After the event, we received a lot of positive feedback about the talk from both the AACT members and non-AACT toxicologists. This event was organized by Drs. Alex Xu, Sherwin Yan, Qihong Huang and Xi Yang. Dr. Ying Huang's presentation is available at:

<http://www.toxicology.org/groups/sig/aact/images/AACT%20webinar.presentation.Huang.final.pdf>



*Dr. Huang is a Pharm/Tox master reviewer at FDA/CBER/Office of Tissues and Advanced Therapies & Division of Clinical Evaluation & Pharmacology/Toxicology. (2004 – present)*



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## **A Huge Success of AACT Delegation to CSOT Conference and CFDA**

— **Conference Note from**

**Dr. Qihong Huang & Dr. X. Sherwin Yan**

On October 15-18, 2017, the 8th Chinese Society of Toxicology conference (CSOT/VIII) was held in Jinan, Shandong, China. More than 1700 scientists attended the conference, making it an unprecedented gathering of Toxicologists in China. Prof. Pingkun Zhou, President of CSOT, made the keynote speech. He reviewed the history of Toxicological Sciences over the century and looked ahead the bright future of the discipline.

A delegation of ten experts from Association of Chinese in Toxicology (AACT) was honored to participate in the CSOT conference. Six delegates held a dedicated platform session on Nonclinical Safety Assessment Strategy in Support of Development of Advanced Therapy. The speakers were Dr. Alex Xu from China FDA (CFDA), Dr. Yi Jin from WuXi AppTec, Dr. Matt Liu from Regeneron, Dr. Ting Su from Bristol Myers Squibb, Dr. Qihong Huang from Boehringer Ingelheim, and Dr. Robert Li from Genentech. The session was chaired by Dr. Alex Xu and Dr. Robert Li. The session covered a wide variety of topics on the Development of Advanced Therapy, representing the most state-of-the-art thinking and approaches in safety assessment in pharmaceutical industry. The session was highly attended and all the talks were well received.

Dr. X. Sherwin Yan from Honeywell International gave a speech in the Section of "Risk Assessment for Pesticides, Cosmetics and New Chemicals". In his presentation Dr. Yan provided an empirical and multi-tier approach to the human exposure and

health risk evaluation of emissions that involves hundreds of substances from fragranced consumer products. Dr. Pan Chen from Albert Einstein College of Medicine attended the Section of "Neurotoxicology of Heavy Metals and POPs". In his presentation Dr. Chen elucidated the novel role for HPO-9/BTBD9, a restless legs syndrome associated protein, in regulating Mn homeostasis and dopamine signaling through the insulin-like growth factor (IGF) signaling pathway in *C. elegans*. Dr. Zhibin Wang from Johns Hopkins University, presented in the Section of "The Current Research Status and Future of Genetic Toxicology". In his presentation Dr. Wang discussed two approaches to identify unknown imprinted genes in exploring the mechanism of regional "autosomal chromosome inactivation" in human development and public health. These presentations represented the leading scientific research and applied approaches in their respective area using the world-class technologies in promoting toxicology in human health evaluation. The topics were up-to-date, the propositions were pioneering, and the approaches were world-class. All sections were highly attended and positive feedbacks received from the audience in each section.

Following the CSOT, four of us were invited to CFDA Center for Drug Evaluation (CDE) in Beijing, where we were welcomed by Dr. Alex Xu (Center Chief Scientist in Pharmacology and Toxicology), Dr. Qingli Wang (Director, Department of Pharmacology and Toxicology) and Dr. Haixue Wang (Deputy Director, Department of Pharmacology and Toxicology) and many pharmacology and toxicology reviewers. The topics of the presentations were Complexities in the preclinical development of antibody drug conjugates by Dr. Matt Liu, Toxicology Issue Resolution

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by Dr. Ting Su, Nonclinical Safety Assessment of Intravitreal Biologics by Dr. Qihong Huang, and Biological Advances to Help Negate the Nonclinical Safety Assessment Strategy in Cancer Immunotherapy by Dr. Robert Li. Dr. Alex Xu also gave a presentation about Challenges on Nonclinical Safety Evaluation of Biologics and Considerations from the Regulatory Perspective. The wonderful presentations drew a great deal of interest and sparked a live discussion between the speakers and the reviewers.

Our delegation to China has come to a successful conclusion. It was a wonderful and memorable journey to each member of the delegation. This trip not only played a chemical risk assessment, and safety assessment of pharmaceuticals, it also had a far-reaching major role in promoting scientific communication on medical research, chem-impact on creating a safer and healthier environment. We all felt truly honored to be part of the AACT delegation participating in the 8th Chinese Society of Toxicology conference (CSOT/VIII).

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**CSOT Conference and CFDA Group Picture**

October 15-18, 2017,  
Jinan, Shandong, China

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## **2017-2018 AACT Community Service**

Dr. Gary Miller, Editor-in-Chief of *Toxicological Sciences*, and Dr. Wei Zheng, Chair of the SOT Board of Publications, have been invited to attend the Chinese SOT meeting in Jinan, China. To help promote the presence of *Toxicological Sciences* in China, AACT was invited to translate some of the journal material into Chinese, which were distributed widely during the meeting in Jinan. This service has been used as a strong evidence for our SOT Global Initiatives Funding application. We would like to acknowledge the following volunteers, Drs. Shuangwei Li, Jian Zhang and Xi Yang, for their invaluable services.

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## 2017-2018 Good News from AACT Members

### Award

1. **Jia-Sheng Wang**, PhD, MD: Dr. Wang has been awarded the 2018 Translational Impact Award from the Society of Toxicology. He is Past President of AACT (2011-2013) and FSSS (2009-2010), Georgia Athletic Association Professor in Public Health and Head of Environmental Health Science Department at the University of Georgia College of Public Health.



**Graduate Students and Dr. Jia-Sheng Wang**  
Winter Graduate Commencement. Friday,  
December 15, 2017, University of Georgia,  
Athens, GA.

### Job changes

1. **Z. Alex Xu**, PhD, DABT: 2017 年作为药理学首席科学家，加入中国国家食品药品监督管理总局药品审评中心。 Chief Scientist in Pharmacology and Toxicology, CFDA Center for Drug Evaluation (CDE) in Beijing
2. **X. Sherwin Yan**, MD, PhD, DABT, ERT: Dr. Yan joined Honeywell as Director of Product Stewardship & Toxicology; he is the current Vice President of AACT.

3. **Tao Wang**, MD, PhD, DABT: Dr. Wang Joined Achaogen, Inc. as Director of Toxicology. She has responsibility for all toxicology functions across early and late stage development programs, including non-clinical safety testing strategies, operations, outsourcing, and budget. Dr. Wang has been an active member at SOT. Currently she serves on the SOT Council as a Councilor.

### Leaderships within SOT

1. **Karin Ke**, PhD, DABT, ERT: Vice President of the Food Safety Specialty Section and will become the President next year.
2. **Xi Yang**, PhD, DABT: Member of Contemporary Concepts in Toxicology Conference (CCT), Liaison for "Toxicological Concerns in Older Adults, a Neglected Majority", which will be held on March 10, 2018, immediately before the 57th Annual SOT Annual Meeting in San Antonio, Texas.

### Achievements

1. **James Yan**, MD, PhD, DABT:再鼎醫藥 (Zai Lab LTD.)成為近期赴美上市的中國藥企，該檔股票 20 日以 18 美元上市 Dr. James Yan has been an Executive Vice President and Head of Early Development & Drug Safety at ZAI Lab Limited since 2015.

### Reminder

Feb. 9, 2018 is the last day for non-on-site registration of 2018 SOT Annual Meeting in San Antonio, Texas. Please come and support AACT activities on Monday, March 12 at the AACT Reception and Workshop.

**AACT newsletter is currently maintained by Dr. Xi Yang and Jun Zhou. If you have materials or information to share with us, please contact with either of them via [yangxi@gmail.com](mailto:yangxi@gmail.com), or [toxicologyjun@gmail.com](mailto:toxicologyjun@gmail.com). Best wishes for your X'mas!**