

Report for SAPA-GP Workshop on Non-Clinical Drug Safety Evaluation



Drug safety is one of the leading factors contributing to the low success rate for drug development. In order to address many issues in drug safety and provide an opportunity for members to better understand key aspects of this field, SAPA-GP organized a workshop on non-clinical drug safety evaluation on December 12, 2009, at Pinecrest Country Club in Lansdale, PA. The attendees included over 100 professionals with various backgrounds, such as chemistry, biology, law, business development, as well as others of diverse backgrounds.

Dr. Yun Zhang, Research Fellow from Merck and Dr. John (Zhihua) Zhang, Vice-President of Preclinical R&D from EnzymeRx were the Co-Chairs for this workshop. They, along with the other nine speakers, are all senior scientists or managers, who have extensive experience in Drug Safety. As discussed briefly below, their presentations covered almost all aspects for this field, from basic science of toxicology to practical considerations in safety evaluation, from small molecules to biological drugs, as well as outsourcing toxicology studies to CROs in China.



(One speaker was giving a talk)



(Lunch and networking)

First, Dr. Jingsong Wang, President-Elect of SAPA-GP and Director for Discovery Medicine & Clinical Pharmacology at Bristol-Myers Squibb, welcomed all guests to this conference and briefly introduced the organization and recent events for SAPA, especially SAPA-GP. Then, Dr. Yun Zhang gave a high-level overview for safety assessment function at different stages of drug R&D and on how the speakers would cover those areas in the program.

The first speaker was Dr. John Erve, Principal Scientist II from Pfizer. He introduced the audience to basic concepts and general principles of drug metabolism and its role in drug toxicology, with numerous concrete examples of drug development failures due to metabolism issues.

Then Dr. Weiping Xiao, Research Fellow from Merck, presented the strategies and major techniques currently in use for predictive safety testing from the discovery to the advanced pre-clinical stage. These assays, including biomarker work, were frequently used to support safety Lead Optimization (LO) and drug development.

After a brief coffee break, Dr. Li Li, Principle Fellow from Novartis, concentrated his talk on overall toxicology program strategy to meet regulatory needs with regard to toxicology for supporting new drug development and registration.

Later, Dr. Haisong Ju, Associated Director from Novartis, discussed the critical roles of safety pharmacology in pharmaceutical industry, with many study examples of safety evaluation in cardiovascular system with emphasis on QT prolongation and associated risk.

Genetic toxicity testing is another important component for drug safety evaluation. In order to cover this complicated area, Dr. Chunhua Qin, Senior Research Genetic Toxicologist from Merck with more than 20 years relevant experience, presented the basic principles of genetic toxicity testing, regulatory requirement and risk management.

Following the lunch break, Dr. Robert M. Parker, Director of Developmental and Reproductive Toxicity (DART) at Huntington Life sciences, gave a talk on preclinical studies for assessing DART. Dr. Parker has been in this specific field for more than 30 years with experience of leading over 300 safety evaluation studies. His talk highlighted some regulatory differences in the US, Europe, and Japan, regarding the design and timing of DART studies in relation to the clinical trials.

Carcinogenicity assessment is a special part of drug safety evaluation due to its importance, as well as its high cost and long duration. Dr. Yi Jin, Senior Project Team Member at Novartis analyzed all aspects of carcinogenicity study and the current regulatory requirements.

In recent years, many pharmaceutical companies have been paying increasing attention over biological drugs, but the toxicities and safety evaluation for biological drugs are quite different from small molecule drugs. Because of that, Dr. John Zhang, Co-Chair of this workshop, gave a special talk to address the unique aspects for non-clinical safety evaluation on biological drugs.



(Exhibition from Nexcelom Bioscience)



(Exhibition from ingenious Targeting Laboratory)

The workshop ended with two talks on the growing toxicology CRO business in China. The first speaker was Mr. Kewen Jin, M.D., the general manager of Charles River Laboratories China, a former SAPA president and one of current SAPA board members, has been involved with CRO business in the pharmaceutical industry for many years. His talk provided the audience with an update on the emerging CRO business in drug safety evaluation in China. Then, Dr. Ernest Bush, Managing Director, China preclinical management services, Vice-President & Scientific Director of Cambridge Healthtech Associates, gave a summary of the major issues, concerns and benefits of working with GLP CROs in China.

During the conference, there were active discussions through questions and answers between the audience and each of the speakers. Furthermore, the coffee and lunch breaks offered lots of networking opportunities. Many attendees commented that this workshop was a very professional event with outstanding speakers in this important field for drug discovery and development. It was the excellent

program that attracted not only SAPA members, but also many participants without Chinese heritage, as well as guests from outside of the tri-state area, such as Virginia and California, specifically coming for this whole day event.

The organizers thank PCI Pharma for helping provide excellent conference logistics, and appreciate the sponsorship from Nexcelom Bioscience and ingenious Targeting Laboratory (iTL). As always, this event had been supported by the SAPA-GP leadership team and many volunteers. (Reported by Guosheng Wu; Photos by PCI Pharma.)

