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Globalization of Quantitative Pharmacology: First International Symposium of Quantitative Pharmacology in Drug Development and Regulation

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ABSTRACT

An International Symposium on Quantitative Pharmacology in Drug Development and Regulatory Sciences (ISQP) was held October 2007 in Nanjing, China, marking the first time scientists from around the globe gathered to discuss topics related to quantitative pharmacology in China.

Quantitative pharmacology embraces all phases of pharmaceutical research and development, providing a mechanism to bridge decision making from one phase of development to the next, and it facilitates multidisciplinary partnerships through the assembly of both data and models that describe complex biological, biopharmaceutic, and clinical settings.

With the recent trend toward global drug development and clinical trials in developing countries, China has been regarded by many as the next frontier for the pharmaceutical industry. Efforts in China are at an early stage, but it is clear that Chinese scientists embrace the discipline and are keen to promote this methodology in the registration of new drugs in China. While challenges exist, they represent an exciting area of future collaboration.

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SYMPOSIUM OVERVIEW

The meeting was sponsored by the Chinese State FDA (SFDA), the Chinese Society of Quantitative Pharmacology, Chinese Society of Pharmacokinetics, and the Chinese Journal of Clinical Pharmacology and Therapeutics and co-sponsored by the American Association of Pharmaceutical Scientists, the American College of Clinical Pharmacology.

Professor Ruiyuan Sun, President Emeritus of the Chinese Society of Quantitative Pharmacology and Editor-in-Chief of Chinese Journal of Clinical Pharmacology and Therapeutics served as the President of the Organizing Committee. International Vice Presidents are Dr. Jun Shi and Prof. Jeffrey Barrett.

In total, 350 attendees, 49 of which came from the United States, Europe, Korea and New Zealand, representing academic, regulatory and industrial communities, participated in the three-day workshop. The Chinese participants spread over 140 different sites covering 25 cities in China.

The meeting featured a plenary morning session each day with two break-out sessions each day. Symposium topics included drug and biological development and regulation sciences, model-based drug development, bridging strategies to support global drug development and clinical policies and guidelines on clinical trials and drug evaluation and approval. The symposium discussed the latest methodologies in pharmacometrics areas focusing on PK/PD modeling and simulation in drug development, regulation and clinical applications.

Two topics were unique and timely given the current issues in global drug development and registration: a) new approaches to studying Traditional Chinese Medicine (TCM) and b) the complexity of the global regulatory review and registration process with emphasis on the evolving demands on the SFDA. Four lectures on the SFDA mission, goals and practices and seven lectures on various research efforts associated with TCM development were provided. The benefit of how quantitative pharmacology research can advance both topics was the central theme of the entire meeting.

REFERENCE *Jeffrey S. Barrett, Jun Shi, Haitang Xie, Xiaohui Huang, Michael J. Fossler, Ruiyuan Sun. Globalization of Quantitative Pharmacology: First International Symposium of Quantitative Pharmacology in Drug Development and Regulation. The Journal of Clinical Pharmacology. 2008 (In Press)*

THREE PRIMARY THEMES

Traditional Chinese Medicine

Chinese pharmacotherapy has included botanicals for many years and TCM represents a significant proportion of the medicines prescribed in China. This meeting provided an opportunity to examine how to characterize some of these complex drug products while leveraging the longstanding clinical experience with these agents. Several presentations addressed the strides being made to close the gap in information regarding TCM.

Regulatory Review: Global Differences in Approach, Process and Decision Making

The State Food and Drug Administration of China (SFDA) has existed for less than 25 years. Great progress has been made in China via the creation of a codified system similar to that used in nations supporting international harmonization though significant issues remain. Most of the didactic presentations were in areas related to worldwide registration and the strategies used in ICH countries. The biggest discord between the current SFDA practices and the concerns of global innovator companies has to do with the definition of what constitutes a "new chemical entity" and the lengthy time required for clinical trial approval in China which precludes participation in many global trials. This was discussed in a roundtable discussion with representatives from the SFDA, international companies, local drug companies and research institutes.

Applications of Quantitative Pharmacology

The ISQP meeting featured several academic, industrial and regulatory applications of quantitative pharmacology from Chinese and Western perspectives. Dr. Thaddeus Grasela gave a keynote presentation on "Delivering on the Promise of Pharmacometrics." Other areas of interest and application included disease/drug/trial models, response surface modeling, model-based strategies in drug development with case studies, values of meta-analysis, adaptive design, modeling and simulations in translational research, drug development and approval, mixed-effect modeling of drug-related QT effects, quantitative pharmacology applications from discovery to development, etc.

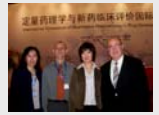
CONCLUSIONS

While pharmaceutical research and development has been pursued on a global scale for many years, it is only recently that these efforts have been extended to all countries of the world. All sectors of the pharmaceutical research community are equally exposed to this phenomenon and will likely participate in the globalization of pharmaceutical R&D in both common and unique ways.

Quantitative Pharmacology embraces all phases of pharmaceutical research and development, providing a mechanism to bridge decision-making from one phase of development to the next. While such efforts in China are at an early stage, it is clear that Chinese scientists embrace the discipline and application and are keen to promote this methodology in the registration of new drugs in China. While challenges exist, they represent an exciting area of future collaboration.

Expectations should be high for the continuation of efforts to globalize the application of quantitative pharmacology in various settings in which the research and development of drugs is explored. The extension of these efforts not only unites talented scientists worldwide but also expands the R&D space promoting new ways of looking at old problems.



MORE INFORMATION: STATUS OF PHARMACOMETRICS RESEARCH IN CHINA

In China, Pharmacometrics (also called Quantitative/Mathematical Pharmacology in China) and its professional society "Chinese Society of Quantitative Pharmacology" were founded in the 1980s by Prof. Ruiyuan Sun and a few others. Since then, this multidisciplinary field has been receiving a great deal of attention and many papers (clinical pharmacokinetics/pharmacodynamics, PK/PD Modeling, PopPK, Pharmaceutical Statistics, etc) have been published in scientific journals. In the meantime, professional PK/PD softwares (3P87, NDST, DAS, etc) have been developed, and monographs, e.g., "Quantitative Pharmacology (1987)" and "New Concepts of Mathematical Pharmacology (2004)" etc, have emerged.

However, the opportunities of quantitative pharmacology in drug development are relatively limited due to generics oriented business model. With its large population, China offers an attractive treatment naïve patient base and deep talent pool. Many international companies started outsourcing discovery and development to China. In the meantime, many Chinese clinical pharmacology institutes are transitioning to GCP compliance CROs for conducting trials. In the near future, it can be anticipated that China will be integrated into global drug development and approval, and the model based drug development paradigm will foster this advancement.