

Opening and Welcome Speech

Mrs Werawan Tangkeo

The Deputy Secretary General of Thai Food and Drug Administration

@ The Siam City Hotel, Bangkok

2-6 February 2009

Dr Viner, Dr Stevens, Dr Sato, and Dr Sudhichai,

Distinguished participants,

Ladies and Gentlemen:

It gives me a great pleasure to welcome all of you and chair the Opening Ceremony this morning to the "Advanced Workshop: Review of Drug Development in Clinical Trials" jointly organized by Asia Pacific Economic Co-operation and Food and Drug Administration, Thailand.

The significance of Drug Clinical Trials and Capacity Building for Drug Regulatory Agencies are well noticed by several international networks including ASEAN or Association of South East Asian Nations, APEC or Asia Pacific Economic Cooperation, and ICH Global Cooperation Group. This project has been endorsed by ASEAN Working Group on Technical Cooperation in Pharmaceutical (AWGTCP), APEC Life Sciences Innovation Forum (LSIF) and ICH Global Cooperation Group (GCG) since the year 2002, 2006 and 2007, respectively.

By the listed international cooperation, indeed, we have received technical, financial, and moral supports. Please allow me to recall the last year achievement of hosting 2 training workshops in Thailand, those are "Preliminary Workshop : Review of Drug Development in Clinical Trials" and "Basic Workshop on GCP/ Clinical Research Inspection".

The accomplishments of both mentioned courses have brought to the 2nd project endorsement by APEC in later of the year 2008. Therefore, Thai FDA again is able to organize the 2nd or advanced phase of the training courses, which include the advanced course of clinical trial assessment and advanced course of clinical trial inspection.

Today's workshop would include numbers of advanced topics regarding the drug development in clinical trials and their assessments to ensure quality and safety of the

clinical trials and the investigational drugs themselves. This workshop has been designed to be practical with lectures, examples and exercises to provide skills, encourage participation and exchange information.

Today's workshop is attended by 4 speakers representing both leading Drug Regulatory Agencies and Industries, those are Health Canada, Pharmaceutical and Medical Device Agency (JAPAN), and Novartis, and officers from Drug Regulatory Authorities of 10 different economies and country including Brunei, Chile, Indonesia, Malaysia, Peru, Philippines, Saudi Arabia, Singapore, Chinese Taipei, and Thailand. Therefore, this workshop will provide us not only essential knowledge but also a great opportunity to share experiences both technical and regulatory issues

I would like to take this opportunity to express my sincere thanks to the organizers and in particular our honorable speakers. All of them have been working with us since the beginning of the planning stage and they are still here today for all of us, even though they are both very busy with their responsibilities at their agencies. We truly appreciate your dedication. Again, this training program could not have been made possible without APEC, ICH, ASEAN, Health Canada, PMDA, and Novartis , who foresee the importance of Clinical Trial Assessment. I hope that everyone would take the results of this program to develop our regulatory system to ensure the quality and safety of clinical trials and investigational products.

Finally, this is an opportune time for me to declare the official opening of the "Advanced Workshop: Review of Drug Development in Clinical Trials" and I wish all 5 fruitful days of interesting and beneficial program and also that you have a pleasant stay in Bangkok.

I warmly welcome you again.