Evolution of Clinical Trial Regulations in Korea

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Thanks to lots of effort and collaborative work among Industry, Academia, and Government, Korea is now appearing as one of very attractive Clinical trial country in the world. There has been big increase in number of multinational developmental studies and also local developmental studies. There has been big improvement of time for Clinical Study authorization. There has been big improvement of Quality.

All those efforts & improvement could be summarized as follows.

1) Regulatory milestones
   a. KGCP implementation according international harmonized ICH-GCP, 1999
   b. Implementation of Bridging study according to ICH-E5, 2000
   c. Implementation of IND, 2001
2) Conceptual change
   a. Clinical research as human experiment
   b. Clinical research as competency for the development of medicine
   c. Clinical research as one of market
3) Organizational change

In order to be evolved more, there would be clear need to do more teamwork and communication among Industry, Academia, and Government. The future direction for Clinical Research environment will be more focus on resource development, quality improvement, and communication & harmonization.

Reference:

1. Korea Pharmaceutical Affairs Law
2. Korea Pharmaceutical Affairs Reinforcement Act
3. Korean Good Clinical Practice
4. Korean Guideline for IND submission

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Dr. Won-Sik Lee is currently Medical Director of Pfizer Korea as of August 2006.

Prior to joining Pfizer, he led the medical department of Sanofi-Aventis Korea since 2001, and worked at MSD Korea for five years before that. Before starting his carrier in the pharmaceutical field, Dr. Lee served as the department chief of the Department of Family Medicine & Health Improvement Center at the Kangnam Sacred Heart Hospital of Hallym University.

Dr. Lee has held important positions in the past and has been active in Clinical Research, Medical service, and Regulatory affairs. He has been working for the Korean regulation on IND and NDA as a taskforce team member and key opinion leader development in Clinical Research, Regulatory Affairs, Pharmacovigilance. So that he improved the quality of Phmacueticals environment. Also, Dr. Lee participate National Technology Roadmap with KSKPT (2002) and the Common Technical Document for Clinical Trial Technology Task Force for KFDA (2003), etc.

From 2000 to 2004, Dr. Lee was the director for Training & Education, Korea Society of Pharmaceutical Medicine and the Korean Research Pharmaceutical Industry Association as chair for regulatory committee from 2003 to 2004.

Since 1999, he has been the member of Clinical & Regulatory Affairs Committee of Korea Pharmaceutical Manufacturers' Association.

He organized the variety academic and industrial activities as facilitator and presenter.

Dr. Lee received the award from the commissioner of Korean Food and Drug Association for the devotion on Public health through quality safety surveillance for medicine (2001).

Dr. Lee graduated from the College of Medicine, Seoul National University and earned a master in Pharmacoepidemiology from Seoul National University and a PhD in Pharmacology from Hanyang University. He also received specialty training in family medicine at Seoul National University Hospital.