



## A Symbol of Excellence

### Interview partner:

**Kim Jong Ran,**  
**DVM, PhD, DACVP**  
*Director of Clinical  
 Operations, Korea, China  
 and Hong Kong*  
*ICON Clinical Research*



*Jong Ran Kim is Director of Clinical Operations for North Asia (China, Hong Kong and Korea) at ICON. She has over 15 years of experience in the pharmaceutical, biotechnology, CRO industry as well as scientific research. Jong Ran started her career as a Researcher at Samsung BioResearch Institute and then moved to a biotechnology company developing oxygen carrier in the blood where she was involved in preclinical and the first human phase 1 studies. She has also worked for Eli Lilly starting at CRA level progressing her career to Clinical Research Manager and then to Quality Manager for Asian operations covering China, Korea, Taiwan and India as well as South East Asia. She has a Masters Degree in Bioscience majoring Genetic Engineering from Korea University.*

#### 1. What is the clinical trial landscape in Korea?

*Korea Adapted ICH-GCP in 2000 and has been implementing KGCP since 2001. Life expectancy for women is 81 and 79 for men, therefore disease incidence rate for chronic diseases such as Cardiovascular and Metabolic disorders is increasing.*

*96% of Koreans are registered in National Insurance Program and this drives patients to look for medical treatment for the disease and higher patient pools for clinical trials.*

#### 2. What are the advantages of conducting clinical trials in Korea?

*Korea has well established investigator sites with experienced investigators and site staff. These are generally centralized in the capital, Seoul. Start-up times in Korea are competitive with other Asian countries, with well defined regulatory, IRB and contract process.*

#### 3. What is the climate for drug development in Korea and how is this supported locally?

*Korea's Pharmaceutical market is worth 17 billion. This makes it the third largest pharmaceutical market after Japan and China in the region and it has continued to grow in double digits since 2002.*

*The government has invested a total of \$ 60 million to establish 15 regional clinical trial centers which are designed as support centers to the clinical trial activity in certain geographic regions. It is actively encouraging the institution to attract more clinical trials*

*Apart from the market size and potential, Korea has a regulatory system which protects the patent of new drugs and facilitates an efficient environment for clinical research. Korea also has become more popular for clinical research to provide Asian data as part of global clinical trials.*

#### 4. What are the challenges in Korea?

*KFDA approval can take approximately two to three weeks and this can affect the study start up time. In addition to this the average experience of local CRAs is shorter than in US or Western Europe as the clinical research industry has only really taken off since 2002*

#### 5. What are some of the ways ICON has overcome these?

*ICON has established a strong Regulatory expert team, led by a manager who has more than 15 years industry experience working with regulatory staff managing the IND and NDA process. Based on this extensive regulatory experience, ICON Korea is providing advice to clients that will help to expedite the regulatory process. We are proving successful in providing this regulatory supporting in complex studies and have a proven record in average turn-around time from submission to approval.*

*We are also actively involved in training programs supporting investigators and site staff to contribute to their development such as a training program with Yonsei Medical Center and we are also involved in training by KoNECT. ICON Korea has a proactive program to identify the investigator sites which are well established and eager to participate in studies in order to provide the best investigator network for patient enrolment and quality.*

*Our staff are very experienced in clinical research and highly qualified with 50% of CRAs being registered pharmacist, 40% are registered nurses and the remaining 10% have BSC in medical sciences.*

#### 6. What fueled the decisions to set up an office there?

*Most of hospitals in Seoul have clinical trial centers which include one stop clinical trial support including; study coordinators, continuous training for investigators, dedicated pharmacy and pharmacist, archiving facilities and dedicated monitoring rooms. Also patient pools are centralized in big university hospitals that are mainly located in Seoul therefore there are excellent representation of patients in these hospitals regardless of disease incidence rate..*

*Korea boasts a higher number of patients enrolled per site compared to other countries which drives a lot of efficiencies to manage the project. It also takes much less time to travel to site for monitoring due to centralization of sites in Seoul which can bring cost effectiveness to the studies*

*Another factor was that Korean pharmaceutical and biotech companies have started to focus on R&D activities, having previously developed strong experience in manufacturing. As Korean pharmaceutical companies look to become more involved in clinical development they are searching for reliable CROs that can provide the broad spectrum of services from regulatory consulting, clinical development activities through to NDA filing and this presented business opportunity for ICON.*

#### 7. What sort of facilities/personnel do you have in Korea?

*The ICON Seoul office was established in 2005 and currently has a total of 62 staff working in the office covering clinical operations, regulatory services with wide therapeutic expertise. We have ISO certification in this office since May 2009 and had a sponsor audit by KFDA in Mar 2009*

#### 8. What are the future plans for your firm as it relates to the countries and the region as a whole.

*ICON will continue to invest and focus on Asia to increase our capabilities in clinical operations and to introduce various services that are driven by the demand by clients.*