Korea Institute of Toxicology â?? Lee Sang-Joon, President

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The Korean Institute of Toxicology (KIT) is a government-funded research institute that evaluates the safety of medicine, bio-related products and chemicals. PharmaBoardroom talks to Lee Sang-Joon, President of KIT about his current operations and his vision for the future.

Can you discuss the role that KIT plays today and some of the activities the institution is currently involved in?

Established in 1980, KIT plays a leading role in improving advanced technology and building the research framework for safety assessment in Korea ranging from tests for general toxicology to tests for environmental toxicology. In addition, we also make up the core infrastructure of Koreaâ??s biotechnology industry and the basic research base for public health and human welfare.

Safety assessment technologies are critical to the development of any drug, most notably in preclinical and Phase I studies. For you, what are your biggest challenges today leading the institute?

Experiments on animals are cruel, expensive, and often inapplicable. However, finding an alternative to animal testing is a challenge we face. We are working hard to find alternatives to animal testing such as *in vitro* methods. However, there are a lot of limitations when using a well-defined *in vitro* system that can often lead to new drugs not making it to market.

As a counter effort, we take animal welfare seriously and were accredited for the first time in Asia as a qualified institute for AAALAC in 1998. More than 10 percent of our employees possess a DVM, (Doctorate of Veterinary Medicine), which compared to the worldwide average is significant.

KIT uses non-human primates during pre-clinical trials due to their similarities with humans. What is the importance of non-human primates testing and how do you position yourself against other similar research facilities?

Given that non-human primates are the humanâ??s closest relatives, the toxicity test using such animals produces the most reliable data that can be easily extrapolated to the clinical studies.

This is especially true for non-human primate tests frequently used for bio-technological pharmaceuticals (biologics) because, in many cases, it is difficult to predict the toxicity of such products in human based on rodent toxicity results. We try not to use non-human primate testing, but often there is no effective replacement.

Over the past 5-6 years, many domestic and international pharmaceutical companies have been interested in the development of biologics, and KIT has lots of experiences in performing studies with antibodies, recombinant proteins, hormones and oligonucleotides. Especially in the testing of oligonucleotides, KIT is one of the top organizations in the world. Having many DVMs is a strong advantage in testing with non-human primates. A certified animal clinic is located inside KIT, so that a full veterinary service is provided to non-human primates if necessary. Animal welfare is a priority to us, and we have been accredited and certified at the very highest level.

The institute engages in research in a number of areas, such as Toxicogenomics. What are some of the most exciting projects you are currently working on?

According to a new paradigm in the field of toxicology, we have focused on developing the alternative toxicity method based on omics, stem cell, tissue engineering, imaging, and *in silico* technology. For omics technologies, we have investigated the toxicity biomarkers using genomic approaches to monitor the toxicity such as hepatotoxicity. For the stem cell and tissue engineering technology, we are developing the alternative cell models for hepatotoxicity, cardiotoxicity, and neurotoxicity. Recently, we have started to investigate the *in silico* model to predict toxicity based on experimental toxicity data and omics data as well as public database.

R&D parts at KIT have investigated the alternative toxicology to provide a better scientific understanding and more adequate data to predict the adverse effects of chemicals on human health. Many research projects in R&D part have been funded from the Ministry of Science, ICT, and Future planning or the Ministry of Trade, Industry and Energy.

The vision of R&D part is to support the drug and new chemical discovery by developing the alternative and predictive toxicity testing method. We expect these approaches to generate data that is more suitable for the assessment of human toxicity than data obtained by current animal test.

What has been the reaction and interest by multinational pharmaceutical companies to your work in COPD?

At KIT, we are focusing on the next generation of preliminary delivery systems. We have in-house physicians and mechanical engineers who are able to design and manufacture inhalation systems as well as a suite of testing rigs that can test the intracellular action driven by inhaled test articles through respiratory organs.

We have a number of inhalation testing rigs that allow us to expose animals for an extended period of time to cigarette smoke, recreating asthma and preliminary bronchitis. Having recreated COPD symptoms in animals, typically rodents, we use noninvasive imaging tools to identify what is happening in the pulmonary region. The facilities we use for our inhalation toxicology studies was only completed in 2008, so this is really just the starting point and we are excited to see what

happens next.

What is the international interest in this institute and how do you develop your business overseas?

KIT has a ten-year history in working with global companies. They pay attention to KITâ??s highly educated and qualified staff, the state of the art facility, and high quality of data. Main collaboration areas have been the regulatory toxicology testing, however they are expanding to non-GLP areas, such as research projects and screening work.

Since the second facility has opened in 2010, where non-human primate and inhalation studies are conducted, KITâ??s capability has been increasing. Recently we have seen many institutions involved in inhalation study close down as they were not seen as cost effective and required a lot of expensive equipment. Fortunately, KIT is supported by government, and the government has identified that it is important to maintain a strong expertise in this area. Our overseas credibility on the inhalation work is increasing. This initial process took time as we had to validate the systems and gain the respective accreditations; we are now regularly published in world-renowned journals.

How active is this institute in terms of your participation in international regulation on environmental issues?

As Korea is an OECD member, KIT participates in the international regulation on safety issues through Korean regulatory authorities. We provide our opinion on issues or data generated at our labs. Currently, we are working in conjunction with overseas laboratories to improve COPD regulations for inhalation testing. NC3, an institute located in England, is gathering data from all round the world. We are participating in the project and contributing our data to them which will be used as a basis for the new guidelines.

The institute has been accredited by a number of regulatory authorities around the world, such as the FDA or EMA. As a result of these international safety accreditations, do you believe the institute can serve as a leader for safety in the region?

GLP started out of the US, Europe and Japan. Initially, it took us some time to catch up, and it required us working with foreign companies in order to gain the necessary experience. We had the talent to become a work leader within the bio-sciences, but we lacked the experience. Now we are building up our experience in the field, and it is time for Korea to take the lead.

Looking to the future, how will you assess the success in the long term and what will you need to do in order to achieve this?

The corporate growth of the private sector is key to the joint growth of the organization. KIT is aiming to be a top ten control research organization (CRO) by 2020. To achieve our goal in five years, we will need to increase our budget to $100 million per annum, 50 percent of which will come from overseas sources. As well as develop our five core technology areas; I am confident that if we achieve these steps, we will be a top ten CRO in the world by 2020.

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