

Role of Korea Radioisotope Center for Pharmaceuticals & Collaboration Plan with the New Research Center at Kijang

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1. Introduction

“Supporting Drug R&D using Radioisotopes & Radiopharmaceuticals Development”

Korea Radioisotope Center for Pharmaceuticals (KRICP) is a government-affiliated institution that specializes in radiolabeled ADME, bioimaging, radiopharmaceuticals GLP & GMP. As the only preclinical facility that can handle radioisotopes in Korea, it houses the state-of-the-art equipment run by experts in the field. Its newly built 14,500m² facility is located in the campus of KIRAMS that is also a home of the Korea Cancer Center Hospital and the Research Institute, specializing in radiopharmaceuticals and radiation therapies.

In this presentation, I would like to explain role of KRICP and discuss potential collaborations with the new radioisotope research center that is being built in Kijang.

2. Role of KRICP

Until now, Korea has been reliant on facilities abroad for almost all of its preclinical research using radioisotopes and radiopharmaceuticals. With the emergence of KRICP, Korea for the first time can now perform Radio-isotope investigational research and

develop radiotherapeutic agents, within a fully integrated technology platform that spans research, nonclinical, and clinical studies.

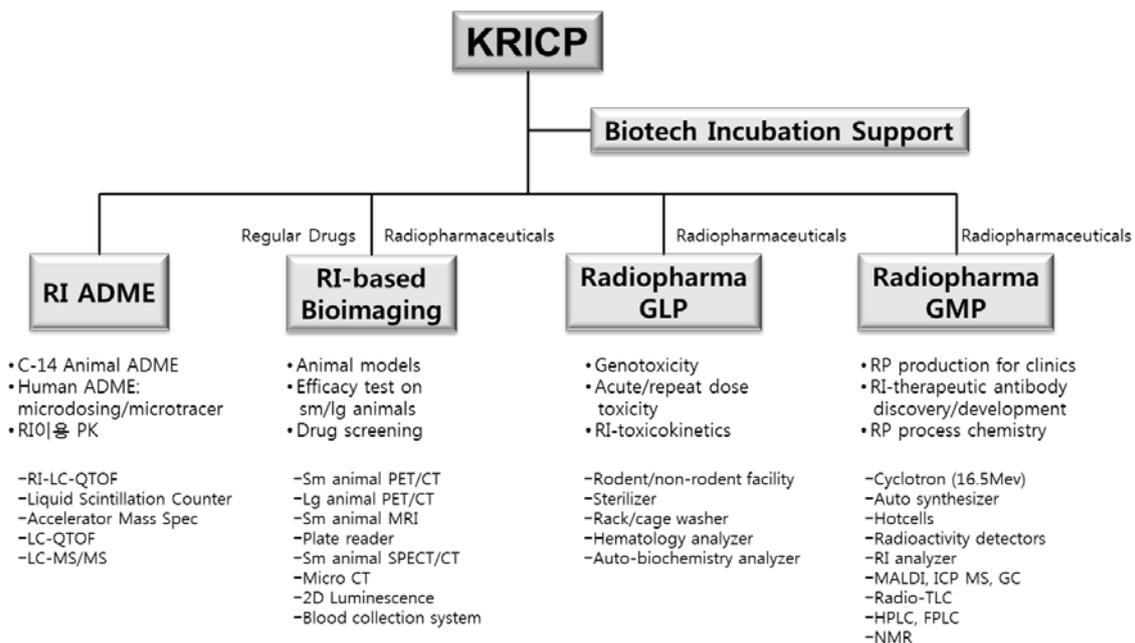
KRICP consists of the following four functional units.

RI ADME

The RI ADME department at KRICP uses its state-of-the-art instruments to measure pharmacokinetics and metabolic processes of drug candidates labeled with carbon-14. In particular, it houses an Accelerator Mass Spectrometer, or AMS. Drugs labeled with ultra-low levels of carbon-14 can be given directly to humans with fewer of the regulatory and safety issues associated with conventional studies. AMS can make clinical development more efficient, reducing overall program costs, while providing the highest level of safety for human subjects

Bioimaging

The Bioimaging facility at KRICP operates a vivarium that can receive external animals, and is equipped with state-of-the-art imaging instruments, including small and large animal PET-CTs, a SPECT-CT, a 9.4 tesla MRI with PET capability, a micro CT, and a Luminescence imager. Researchers can perform non-invasive studies such as drug efficacy, bio-distribution, pharmacokinetics, and dosimetry tests using customized animal models.



Radiopharmaceuticals GLP

KRICP has a GLP toxicology facility for radiopharmaceuticals. It is the only such facility in Korea and will be on par with all like global research centers.

The laboratory has capabilities for single- or multiple-dose toxicity monitoring and genotoxicity assays using either rodent or non-rodent models. This GLP lab will fulfill the needs of radiopharmaceutical researchers transitioning to the clinical stage and is a core part of KRICP's Investigational New Drug enabling total-solution program.

Radiopharmaceuticals GMP

KRICP has a radiopharmaceuticals production facility that consists of 6 individual clean rooms with built-in hotcells, autosynthesizers, and quality control and microbiological testing systems.

Its clean rooms are directly connected to a 16.5 MeV cyclotron that can produce F-18 and C-11, and its auto-synthesizers and auto-distributors can produce radiopharmaceuticals with many commonly used metallic radioisotopes.

Hot cells for research purposes, MALDI-mass spectrometry and ICP-mass spectrometry are available to aid in the entire radiopharmaceutical development process.

3. Collaboration Plan with the Kijang research center

The new research center in Kijang (the Center) focuses on the processing of radioisotope production, development of new utilities of radioisotopes and their commercialization.

The Center's C-14 production program, for example, would provide companies that synthesize the C-14 labeled compounds with the ready access of the source material, which has been monopolized by Russians. These C-14 labeled drugs are to be used in KRICP's RI-ADME program, which then provides preclinical and clinical results in drug development process. Therefore, the Center's major supply chain is the starting point of RI-ADME and the following drug development processes.

Various useful radioisotopes that are planned to be developed at the Center will be the key ingredients of diagnostic or therapeutic radiopharmaceuticals. These radiopharmaceuticals will go through preclinical and clinical processes that utilize KRICP's facility. Thus, the commercialization of radioisotopes at the Center would be fully realized by going through KRICP's programs. The GMP facility at KRICP is also going to act as a key production test bed for various products that the Center planned to develop.

As such, the Center and KRICP can collaborate, either directly or through industry partners, in drug and radiopharmaceuticals development. The full process of

drug development is now in order through collaboration of the Center and KRICP, which will contribute greatly on measuring up the pharmaceutical industry in Korea.