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Key note lecture: Regulatory science and toxicology

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Currently, scientific term “Regulatory Science” has been appeared in scientific fields with various definitions. In Japan, the term “Regulatory Science” has been firstly introduced by Dr. M. Uchiyama, the former Director General of NIH. At the time of 1987, he has defined that regulatory science is the scientific activities to conduct a harmonized application of the multifaceted subjects or products to human society under the proper and accurate assessing and evaluating by using the sophisticated updating sciences and technologies. His most recent definition is that the science is the research activities that support the effort of regulating and optimizing scientific and technological development according to the objectives geared toward human health. Thus, in the toxicological aspects, the targeting objectives and products by regulatory science are chemicals distributed in the human society, such as foods, pharmaceuticals, agrochemicals, industrial chemicals and so on.

Regulatory science on drug regulation provides a scientific basis for fitting a substance into society and to patients as a drug via the regulation process. With respect to food regulatory science, each country has their own standards in order to protect people from contaminated and unknown food ingredients. In other respect, regulatory science is not simply limited to the areas as described above, but also the science could be expanding to various areas even in the individual's daily work.

In turn, toxicology provides scientific evidence with toxic manifestations for evaluating chemicals and others. Traditional toxicology defines toxic manifestations and current modernized toxicology will clarify mechanism of the targeted compound, even epigenetic changes. Therefore, toxicology may play important roles in the development of regulatory science.

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Regulatory science in Asia: current and future aspects of regulatory science in Korea

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As the research and development institute under KFDA, NIFDS has played the key role in comprehensive researches which are necessary for food and drugs regulation in Korea since its establishment in 1995. It has performed development and evaluation on toxicological and pharmacological methods. NIFDS has lead national initiatives on endocrine disruptor researches and published a number of test method and evaluation reports. NIFDS has also run Korea National Toxicology Program (KNTP) and produced toxicology report on 40 natural compounds.

NIFDS has recognized needs for adopting cutting-edge life science technologies to improve conventional toxicology screening methods and to develop better evaluation tools for regulatory science. For this purpose, NIFDS has actively employed emerging technologies such as toxicogenomics, systems toxicology and in silico modeling. We have performed more than 40 microarray projects for toxicology studies and released data for public since 2008. Along with toxicogenomic effort, we have recently initiated a predictive toxicology research program. This program is mainly focused on developing in silico model for toxicity prediction using systems toxicology. Developing alternative test methods is another field of interest for NIFDS. NIFDS is running a program for developing and validating alternative test methods based on 3R principle. NIFDS currently runs endocrine disrupter screening test, eye irritation test and skin irritation test with collaboration of ICATM and already published 6 guidelines for alternative test methods. As safety of nano-materials in food and drugs has become controversial, NIFDS has launched a toxicological research program to evaluate their safety concern. Currently NIFDS runs safety studies on silver, gold and zinc oxide with collaboration of OECD.

NIFDS exerts its effort for developing new toxicity test method by actively adapting emerging technologies and actively participate in international workgroup for modernizing regulatory science. NIFDS will continue its effort for developing new technologies for regulatory science in future by actively adapting emerging technologies.