Hajime Kojima, Madridge J Pharm Res. 2019
http://dx.doi.org/10.18689/2638-1591.a3.002

Japanese Plan on Safety Evaluation of a Chemical with Non-Animal Test Methods

Hajime Kojima
National Institute of Health Sciences (NIHS), Japan

In Japan, a main organization on the alternative to animal testing is the Japanese Center for the Validation of Alternative Methods (JaCVAM). JaCVAM is hereby established as part of the Biological Safety Research Center (BSRC), the National Institute of Health Sciences (NIHS) in 2005 and the BSRC director serves as head of JaCVAM. JaCVAM was established to promote the use of alternative methods to animal testing in regulatory studies, thereby replacing, reducing or refining (the 3 Rs) the use of animals wherever possible while meeting the responsibility of the BSRC to ensure the protection of the general public by assessing the safety of chemicals and other materials, as stipulated in the regulations of the NIHS. JaCVAM activities are also beneficial to application and approval for the manufacture and sale of pharmaceutical and other products as well as to revisions to standards for cosmetic products. Under the International Cooperation on Alternative Test Methods (ICATM), JaCVAM contributed to establish nine test guidelines in OECD.

Recently, JaCVAM (Japanese Center for the Validation of Alternative Methods) is coordinating, along with several other international collaborators, in ongoing validation studies and independent peer reviews, which include Hand1-Luc EST (Embryo Stem cell Test) and Zebrafish embryo toxicity test method for the reproductive & developmental screening and MITA (Multi-ImmunoTox assay) for immunotoxicity in the field of systemic toxicology.

On the other hand, Japanese new projects started last year. One is “Microphysiological System” project supported by AMED (Japan Agency for Medical Research and Development). In this project, a few types of models using Human Organ-on-chips have developed for drug screening by collaborations with pharmaceutical companies and academia, etc. The other one is “Development of AI based next generation safety prediction system using related Big data (AI-SHIPS)” project supported by METI (Ministry of Economy, Trade and Industry). Basic strategy of this project is to develop the prediction system of hepatotoxicity (cytotoxicity, lipid abnormality, cholangiopathy and hypertrophy etc.) and to develop hemo-toxicity and renal-toxicity using the data based on 28-day Repeated Dose Toxicity Test.

For the systemic toxicological endpoints of repeated dose toxicity, carcinogenicity and reproductive toxicity, new test methods are expected to be developed in the future worldwide. I believe Japan will make a significant contribution to these developments in JaCVAM and the Japanese projects.

Biography:

Hajime Kojima, Ph.D., is the secretary general of Japanese Center for the Validation of Alternative methods (JaCVAM) and the section chief of Division of risk assessment, Biological Safety Research Center (BSRC) in National Institute of Health Sciences (NIHS) contributing to the identification and evaluation of *in vitro* test methods for their potential validation, in the field of genotoxicity and local toxicity (skin and eye). He holds several publications in refereed journals dealing with *in vitro* toxicity assay as well as validation study. He is a vice-chair of the Working Group of the National Coordinators for the Test Guidelines Programme and is also an expert of skin & eye irritation, skin sensitisation, validation management group of non-animal for endcrine disrupter in OECD (Organisation for Economic Co-operation and Development). Until now, he has contributed to be approved more than 10 test methods developed by Japanese in the OECD Test Guidelines.