LS-2

Genotoxicity Assessment in Korea and Related Issues

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There are four regulatory authorities in Korea (FDA, NIER, RDA and MOA) and several guidelines concerning genotoxicity tests are available. These authorities require registrants to submit genotoxicity test reports for a part of registration of substances concerned. In Korea the authorities issue GLP certificate to a test facility, and the certificate is for a specific type of test. Currently 17 GLP facilities are in Korea and most of the facilities perform three types of genotoxicity tests, and several facilities have been doing additional Mouse Lymphoma Assay and Sister Chromatid Exchange test also.

For the international harmonization of toxicological studies the National Institute of Environmental Research (NIER) is going to issue a guideline for in vitro mammalian cell gene mutation assay, based on the OECD TG476, to couple with the REACH program.

To meet the future requirements of ICH S2(R1) the National Institute of Toxicological Research (NITR) is currently working on standardization of in vivo and in vitro comet assay and in vitro micronucleus test. NITR is also focusing on the validation of in vivo micronucleus test incorporated into a repeated-dose study.

Early 2008 a council for genetic toxicity test, composed of researchers of 14 GLP facilities, was organized by NITR. Each working group of the council is sharing methodologies of a genotoxicity testing of member’s facility, and aiming to make optimized procedures and contents of education/training of personnel working in this field.