

Approach for OECD Test guideline of alternative methods developed by Japan

Hitoshi Sakaguchi (Kao Corporation)

In the safety evaluation, the data obtained by global standard test methods that are widely used in the world and have a lot of background data, are judged as most dependable. Therefore, it is important whether an alternative method is adopted as OECD Test Guideline.

Currently we are developing in vitro skin sensitization test and eye irritation test, and the final goal of these tests is OECD Test Guideline. In developing the above test methods, I could notice the important points for developing test method as OECD Test Guideline, so I would like to present.

There are mainly four stages by acceptance as OECD Test guideline. 1) Test development, 2) Inter-laboratory study (Ring Study), 3) Validation, 4) Peer-review. In the 1st stage, the role of the lead laboratory is very large, and the development of SOP, making of database, and definition of applicability domain are important items. To evaluate predictive capacity, a database is needed. The number of test chemical in the database is reported about 100 for in vitro skin sensitization test or eye irritation test. The rapid evaluation for these test chemicals leads to shortening at the in vitro test method development period and it is important.

In the Ring Study for evaluation of inter-laboratory reproducibility, the number of test chemicals and testing laboratories, and the selection of tested chemicals are important points. Especially it is needed that the test chemicals will be selected from the lists that were published from COLIPA or ECVAM as standard chemical for development of a new alternative method.

And, it is important to conduct by strategic approach in Validation and Peer-review. From now, the most of Validation and Peer-review will be organized under the ICATM framework as international work. Therefore, it is important that the validation and peer-review for a new alternative method developed in Japan will be done by collaboration with not only JaCVAM but also ECVAM and ICCVAM. The Japanese in vitro skin sensitization, h-CLAT are on going in Pre-validation by ECVAM, and the Japanese in vitro eye irritation test, STE test will be Peer-reviewing by ICCVAM in near future.

Finally our Japanese researchers need to be present and submit as manuscript timely for our data of new alternative methods. It is important to present at not only Japanese meeting but also EU/USA meeting actively, and to be published our data in an appropriate international journal by English.