Title of Research:

18_R01-01

The validation study of EpiSensA (Epidermal Sensitization Assay); the *in vitro* skin sensitization assay based on reconstructed human epidermis

Principal Investigator:

Masaaki Miyazawa, PhD (Safety Science Research Laboratory, Kao Corporation)
2606, Akabane, Ichikai-Machi, Haga-Gun, Tochigi 321-3497, Japan
(tel) +81-80-8466-6147, (e-mail) miyazawa.masaaki@kao.com

Collaborators:

Noriyasu Imai, Megumi Sakuma, PhD, Momoko Shibata (KOSÉ Corporation)
Mika Watanabe, Mayu Ikezumi, Katsuhiro Uno, PhD (Hatano Research Institute, Food and Drug Safety Center)
Shinichi Watanabe, Junko Ueno (LION Corporation)

Summary of Research:

The assessment of skin sensitization potential is a major content of safety evaluation for novel substances and was traditionally performed by animal tests. On the other hand, the development of non-animal tests for identifying the skin sensitization has been recently activated because of animal welfare and regulatory requirements. However, lipophilic chemicals are difficult to correctly evaluate, since these tests employ aqueous-phase systems. To overcome the limitation, we focused on a reconstructed human epidermis (RhE) and developed the Epidermal Sensitization Assay (EpiSensA) based on the gene expression of four markers related to induction of skin sensitization. Based on the comparison with the results of animal test, we confirmed that EpiSensA had the great predictive performance for lipophilic test chemicals. Therefore, the validation study of EpiSensA was started from July 2018 at JaCVAM (Japanese Center for the Validation of Alternative Methods) to adopt it for OECD test guideline.

At current study, the transferability to the three naive laboratories was evaluated based on three sensitizers and a non-sensitizer distributed from Kao Corporation with non-coded. As the results, the concurrent results of EpiSensA compared to animal test were observed with great reproducibility at all laboratories. From these results, we concluded that the technical transfer to three naive laboratories was successfully completed. From November 2018, the Phase I study for the evaluation of with-in laboratory reproducibility have been performed based on 14 test chemicals. After that, the Phase II study for between laboratory reproducibility will be performed from March 2020, and the validation study of EpiSensA will finish at early 2021.

Timeline:

June 1, 2018 – February 28, 2019

Topics:

Poster presentation at 2018 JCIA-LRI Workshop

Publications: