Annual report on the Japanese Center for the Validation of Alternative Methods (JaCVAM) in 2016

Hajime Kojima and Akiyoshi Nishikawa

JaCVAM, Biological Safety Research Center, National Institute of Health Sciences (NIHS)

Abstract

In 2016, JaCVAM (Japanese Center for the Validation of Alternative Methods) proposed three test methods accepted by the JaCVAM Regulatory Acceptance Board to the regulatory agency, including: 1) the Stably transfected Transcriptional Activation Assay to Detect ER mediated activity, 2) the reconstructed human Cornea-like Epithelium Test Method for eye irritation testing and 3) h-CLAT assay for skin sensitization testing.

Furthermore, JaCVAM contributed to approve two OECD (Organisation for Economic Co-operation and Development) two Test Guidelines (TGs). They are 1) OECD Test No. 442E: h-CLAT assay for skin sensitization testing, 2) OECD Test No. 458: Stably Transfected Human Androgen Receptor Transcriptional Activation Assay for Detection of Androgenic Agonist and Antagonist Activity of Chemicals. In the OECD Work plan, Japan has proposed two test methods: 1) the IL-8 Luc assay for skin sensitization testing, and 2) the Reactive Oxygen Species (ROS)assay for photosafety assessment. Additionally, JaCVAM is coordinating, along with several other international collaborators, in ongoing validation studies and peer reviews, which include MITA (Multi-ImmunoTox assay) for immunotoxicity, ADRA (Amino acid Derivative Reactivity Assay) for skin sensitization testing, Hand1-Luc EST (Embryo Stem cell Test) for the developmental screening, and SIRC-CVS (Crystal Violet Staining), Vitrigel-EIT (Eye Irritation Test) and LabCyte Cornea-model-EIT for the eye irritation testing.