

International Workshop on Alternative Methods to Reduce, Refine, and Replace the Use of Animals in Vaccine Potency and Safety Testing

J Kulpa-Eddy¹, R McFarland², R Isbrucker³, M Halder⁴, H Kojima⁵, B Jones⁶, N Johnson⁶, D Allen⁶, E Lipscomb⁶, S Morefield⁶, W Casey⁷, W Stokes⁷

¹USDA, Riverdale, MD; ²US FDA, Rockville, MD; ³Health Canada, Ontario, Canada; ⁴ECVAM, Ispra, Italy; ⁵JaCVAM, Tokyo, Japan; ⁶ILS, Inc, RTP, NC; ⁷NICEATM, NIEHS/NIH/DHHS, RTP, NC

Vaccines represent a vital tool in the prevention of infectious diseases. However, regulatory testing to meet vaccine lot release requirements can involve large numbers of animals that may experience unrelieved pain and distress. To advance scientifically sound alternative methods that reduce, refine and replace animal use for human and veterinary vaccine potency and safety testing, NICEATM/ICCVAM organized an international workshop in partnership with ECVAM, JaCVAM and Health Canada. Nearly 200 scientists from 13 countries participated in this SOT co-sponsored workshop. Workshop participants identified knowledge and data gaps that need to be addressed to develop alternative methods. They also identified and prioritized research, development and validation activities needed to address these knowledge and data gaps, including the application of new science and technology to develop improved methods. They agreed that vaccines that use the largest number of animals and that are associated with the greatest pain and distress should be the highest priority for development and validation of alternative methods. High priorities included implementation and further optimization/development activities for alternative methods for rabies and Clostridial vaccines. Participants also emphasized the need to find ways to avoid or minimize challenge testing with live viruses and bacteria that are hazards to laboratory workers or the environment. Ways to promote the increased use of accepted methods were also discussed. Implementation of the workshop recommendations is expected to advance the use and availability of alternative methods for vaccine potency and safety testing while ensuring continued protection of human and animal health. ILS Staff supported by NIEHS contract N01-ES-35504.

Keywords: vaccine; potency; safety; workshop; alternative; methods

Poster Session: Disease Prevention