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

William H. Natcher Conference Center, Bethesda, MD, USA
September 14-16, 2010

Suggested Reading

Session 1 Overview of Public Health Needs and Regulatory Requirements for Vaccine Testing

History and Overview of Human Vaccines and their Importance to Public Health

History and Overview of Veterinary Vaccines and their Importance to Animal Health

U.S. FDA Requirements for Human Vaccine Safety and Potency Testing
21 CFR Parts 600 through 680

Guidance for Industry for the Evaluation of Combination Vaccines for Preventable Diseases: Production, Testing and Clinical Studies available at:

USDA Requirements for Veterinary Vaccine Safety and Potency Testing
21 CFR Parts 600 through 680

International Regulatory Requirements for Vaccine Safety and Potency Testing: Roundtable Discussion


**Session 1 General References**


**Session 2 Replacement Methods for Vaccine Potency Testing: Current State of the Science and Knowledge Gaps**

Overview of Currently Approved Veterinary Vaccine Potency Testing Methods and Methods in Development That Do Not Require Animal Use


Case Study of Development, Validation, and Acceptance of a Non-Animal Method for Assessing Veterinary Vaccine Potency


**Overview of Currently Approved Human Vaccine Potency Testing Methods That Do Not Require Animal**


**Overview of The Current Status of Human Vaccine Potency Testing Methods in Development That May Replace Animals**


**Case Study of Development, Validation, and Acceptance of a Non-Animal Method for Assessing Human Vaccine Potency**


**Session 2 General References**


Session 3 Animal Use for Vaccine Potency Testing: Refinement and Reduction Alternatives

Session 3A: Refinement Alternatives: Using Serological Methods to Avoid Challenge Testing

Refinement Alternatives for Human Vaccine Potency Testing: Overview of Currently Approved Serological Methods

Refinement Alternatives for Veterinary Vaccine Potency Testing: Overview of Currently Approved Serological Methods

Animal Refinement and Reduction Alternative Approaches for Vaccine Potency Testing of Diphtheria and Tetanus Vaccines

Development and Validation of Serological Methods for Human Vaccine Potency Testing: Case Study of an Anthrax Vaccine

**Development and Validation of Serological Methods for Veterinary Vaccine Potency Testing: Case Study of a Veterinary Vaccine**


**Session 3A  General References:**


**Session 3B: Refinement Alternatives: Using Earlier Humane Endpoints to Avoid or Minimize Animal Pain and Distress in Vaccine Potency Challenge Testing**

**Overview of Current Humane Endpoints in Human and Veterinary Vaccine Potency Testing**


Overview of Current Reduction Methods and Reduction Methods in Development for Vaccine Potency Testing


Application of the Consistency Approach for Reducing Animal Use in Vaccine Potency Testing


Session 3B General References


Session 4  Vaccine Safety Testing: Post-Licensing Reduction, Refinement and Replacement Methods and Strategies

**Human Vaccine Post-license Safety Testing: Overview of Current Regulatory Requirements and Accepted Alternatives**


**Veterinary Vaccine Post-License Safety Testing: Overview of Current Regulatory Requirements and Accepted Alternatives**


**Target Alternative Vaccine Safety Testing Strategies for Pertussis Toxin**


**Current Research and Development Activities Directed Toward Replacement of the Neurovirulence Test in Vaccine Safety Testing**


Session 4  General References
