



**Implementing non-animal approaches to human and veterinary vaccine testing:
Achieving scientific and regulatory success for rabies and beyond**

National Institutes of Health
Natcher Conference Center
Bethesda, Maryland - 16-17 October 2018

Day 1 – October 16, 2018

7:30 **Registration - Poster Set Up**

Session 1 - Welcome from the Organizers

Moderator: Robin Levis, Food and Drug Administration (FDA)

8:30 **Warren Casey**, National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM)

8:45 **Richard Hill**, International Alliance for Biological Standardization – North America (IABS-NA)

Session 2 - Setting the Stage for Alternatives to *In Vivo* Release Testing for Animal and Human Vaccines

Moderator: **Richard Hill**, International Alliance for Biological Standardization – North America (IABS-NA)

9:00 Human Biologics - North American Regulatory Perspective
Robin Levis, Food and Drug Administration (FDA)

9:30 Animal Biologics - North American Regulatory Perspective
Geetha Srinivas, U.S. Department of Agriculture (USDA) – Center for Veterinary Biologics (CVB)

10:00 The “Consistency Approach”: Concept and Progress Since the 2015 Congress
Marlies Halder, European Commission Joint Research Center (JRC)

10:20 Rabies and the Innovative Medicines Initiative, Vaccine Lot to Vaccine Lot Comparison by Consistency Testing (IMI Vac2Vac)
Catrina Stirling, Zoetis Inc.

10:40 **Break and Posters available for viewing**

11:00 Drivers and Barriers to Replacing the NIH Test for Rabies Vaccine Potency Testing
Marie-Jeanne Schiffelers, Utrecht University School of Governance

11:20 A Success Story of Alternatives to In Vivo Testing: Pertussis Vaccine Histamine Sensitization Test (HIST) Waiving and Replacement
Juan Arciniega, Food and Drug Administration (FDA)(retired)

11:40 Substituting *in vitro* for *in vivo* vaccine potency and safety assays: science versus the fear factor
Dean Smith, Health Canada, Center for Biologics Evaluation



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Session 3 – Rabies Vaccines Alternative Testing - State of the Art and Reagent Availability

Moderator: Robin Levis, Food & Drug Administration (FDA)

- 12:00 Reagents and Serology
Marc Fiorucci, Boehringer Ingelheim Animal Health
- 12:20 Animal Health Institute (AHI) Veterinary Biologics Section (VBS) Rabies Potency Test Working Group - Technical and Procedural Perspectives
Nancee Oien, Zoetis Inc.
- 12:40 **Lunch and Posters available for viewing**
- 13:40 Overview of European Partnership for Alternatives to Animal Testing (EPAA) Efforts on Replacement of Animal Testing for Rabies Vaccine and Reagent Availability
Jean-Marie Chapsal, The European Partnership for Alternative Approaches to Animal Testing (EPAA)
- 14:00 Overview of European Directorate for the Quality of Medicines and Healthcare (EDQM) - Efforts in the Rabies Space
Eriko Terao, Council of Europe, EDQM
- 14:20 An ELISA for Human Rabies Vaccine - Method Validation Leading to Selection for EDQM
Audry Toinon, Sanofi Pasteur.
- 14:40 Use of ELISA for a New Human Rabies Vaccine: Clinical Trial for a Dose Ranging Study
Françoise Guinet-Morlot, Sanofi Pasteur
- 15:00 An ELISA for Veterinary Vaccine: Validation and Acceptance by EMA as an Alternative to NIH Rabies Test
Marc Fiorucci, Boehringer Ingelheim Animal Health
- 15:20 Development of In Vitro and In Vivo Rabies Virus Neutralization Assays Based on a High Titer Pseudovirus System
Xuguang (Sean) Li, Health Canada, Regulatory Research Division
- 15:40 **Break and Posters available for viewing**

Session 4 - Charting the Path Forward for Alternative Testing for Rabies Vaccines

Moderator: Laurent Mallet, Sanofi Pasteur

- 16:00 Roundtable 1 – Setting the Stage – Aspirational Outcomes for the Workshop and Roundtables
Introductory Comments: **Laurent Mallet**, Sanofi Pasteur
- Moderators:**
Veterinary Rabies Focus – **Catrina Stirling**, Zoetis
Human Rabies Focus – **Cynthia Allen**, Health Canada, Centre for Biologics Evaluation
- 17:00 – 18:0 **Poster Session** - Alternatives to Vaccine Testing in Animals - Beyond Rabies



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Day 2 – October 17, 2018

Session 4, continued

Charting the Path Forward for Alternative Testing for Rabies

(Veterinary and human focus groups will meet separately for majority of Roundtables)

Moderator: Laurent Mallet, Sanofi Pasteur

- 8:30 Keynote address:
Alternatives to Animal Testing – Rabies and Beyond
Donna Gatewood, EDGE Veterinary Vaccines Consulting Group, LLC
- 9:00 Brief review of Day 1 Progress and Refinements on Roundtable Goals for Day 2
Veterinary Rabies Focus – **Catrina Stirling**, Zoetis Inc.
Human Rabies Focus – **Cynthia Allen**, Health Canada, Centre for Biologics Evaluation
- 9:15 **Roundtable 2** – Ideation and Action (V and H workgroups meet separately)
Moderators:
Veterinary Rabies Focus – **Donna Gatewood**, EDGE Veterinary Vaccines Consulting Group, LLC
Human Rabies Focus – **Dean Smith**, Health Canada, Centre for Biologics Evaluation
- 12:00 **Lunch and Posters breakdown**
- 13:20 Joint Session - Regulatory and industry speakers will highlight specific challenges, methods to expedite research and regulatory changes

Items may include specific challenges, methods to expedite research and regulatory changes
- 13:20 Regulatory Considerations from the Veterinary and Human Perspective
Veterinary Regulatory – **Oksana Yarosh**, Canadian Food Inspection Agency
Human Regulatory – **Philip Krause**, Deputy Director, Office of Vaccines Research and Review, CBER/FDA
- 13:40 Industry Considerations from the Veterinary and Human Perspective
Veterinary Industry – **Catrina Stirling**, Zoetis Inc.
Human Industry – **Laurent Mallet**, Sanofi Pasteur
- 14:00 **Roundtable 3** – Drafting the Roadmap (V and H workgroups meet separately)
Co-moderators from Roundtables 1&2:
Veterinary Rabies Focus – **Donna Gatewood**, EDGE Veterinary Vaccines Consulting Group, LLC and **Catrina Stirling**, Zoetis Inc.
Human Rabies Focus – **Dean Smith**, Health Canada, Centre for Biologics Evaluation; **Cynthia Allen**, Health Canada, Centre for Biologics Evaluation
- 15:30 Break



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Session 5 - Rabies Alternative Testing Wrap-up Global Perspective and Future Considerations

Moderator: Warren Casey, National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM)

- 15:45 Veterinary and Human Roadmaps
Veterinary Rabies Focus – **Donna Gatewood**, EDGE Veterinary Vaccines Consulting Group, LLC; and **Catrina Stirling**, Zoetis Inc.
Human Rabies Focus – **Dean Smith; Cynthia Allen**, Health Canada, Centre for Biologics Evaluation
- 15:45 Veterinary and Human Roadmaps
Veterinary Rabies Focus – **Donna Gatewood**, EDGE Veterinary Vaccines Consulting Group, LLC; and **Catrina Stirling**, Zoetis Inc.
Human Rabies Focus – **Dean Smith; Cynthia Allen**, Health Canada, Centre for Biologics Evaluation
- 16:20 Global Perspective and Future Considerations for Decreasing Testing in Animals
Rebecca Sheets, International Alliance for Biological Standardization (IABS)
- 16:40 Closing Conference Comments
Warren Casey, National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM)
Richard Hill, International Alliance for Biological Standardization-North America (IABS-NA)
Robin Levis, Food and Drug Administration (FDA)

Scientific Program Committee

CO-CHAIRS

Warren Casey, National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM)

Robin Levis, Food and Drug Administration (FDA)

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MEMBERS

Juan Arciniega, Food and Drug Administration (FDA)(ret)

Geetha Srinivas, U.S. Department of Agriculture (USDA) – Center for Veterinary Biologics

Yvette Diamondidis, Zoetis

Cynthia Allen, Health Canada - Biologics and Genetic Therapies Directorate, Viral Vaccines Division

Oksana Yarosh, Canadian Food Inspection Agency

Laurent Mallet, Sanofi Pasteur

Rodney Christmas, Boehringer Ingelheim Animal Health

James Roth, Institute for International - Cooperation in Animal Biologics/ Center for Food Security and Public Health

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Jeffrey Brown, PETA International Science Consortium

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Rebecca Sheets, International Alliance for Biological Standardization (IABS)

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