Tuesday, April 21
7:30  Registration

**Introductory Session**

8:00  Welcome
Jim Roth, IICAB

8:10  Introduction to the Workshop
Byron Rippke, Director, USDA Center for Veterinary Biologics

8:20  Overview of Potency Testing Policy Development
Dave Siev, USDA Center for Veterinary Biologics

8:50  Historical Perspective on Regulation of Potency of USDA Regulated Vaccines
Dave Dusek, USDA Center for Veterinary Biologics
Hans Draayer, EDGE Veterinary Vaccines Consulting Group

9:50  Morning break

**Issue 1: Product Efficacy and Potency**

10:10  Minimum Protective Dose: How it is Established and What it Indicates
Dave Siev, USDA Center for Veterinary Biologics
Tom Evans, Zoetis

11:30  Questions and discussion from audience

12:10  Lunch break
Issue 2: Determining Potency Requirements for Release and Throughout-Dating

1:15  Potency Specifications for Serial Release and Throughout Dating
Monica Reising, USDA Center for Veterinary Biologics
Richard Williams, Merial

2:15  Pharmaceutical Shelf-Life Determination – Findings of the PQRI Stability Shelf-Life Working Group
James Schwenke, Applied Research Consultants

3:00  Afternoon break

3:20  Minimum Potency Throughout Dating and Lot Release Practices of Other Agencies/Countries
Human Vaccines
Philip Krause, FDA Center for Biologics Evaluation and Research

Veterinary Vaccines in European Union (EU)
Examples of EU stability assessments and definitions of release and end of shelf-life specifications, Jacques Léchenet, International Federation for Animal Health Europe

5:20  Questions and discussion from audience

6:00  Evening social hour with cash bar

Wednesday, April 22

Issue 3: Policy Considerations for Different Product Types

8:00  Product-Specific Considerations, e.g. Viral Vaccines (live, killed, vectored), Bacterins, Bacterial Extracts, Toxoids
Dave Dusek, USDA Center for Veterinary Biologics
Mark Zylstra, Boehringer Ingelheim Vetmedica, Inc.

9:00  Questions and discussion from audience

9:30  Morning break
**Issue 4: Points to Consider When Determining Release and Throughout-Dating Potency Specification**

9:50  
**Implications of Potency Specifications at Product Release and Through Dating**  
Scott Taylor, USDA Center for Veterinary Biologics  
Kent McClure, Animal Health Institute

11:20  
**Questions and discussion from audience**

11:50  
**Lunch break**

1:00  
**Assessing and Balancing Risks in the Formulation and Dating Period of Vaccines**  
Francisco Zagmutt, EpiX Analytics

1:30  
**Veterinary Immunology Insights**  
Christopher Chase, South Dakota State University

1:50  
**Questions and discussion from audience**

**Issue 5: Views from Users of Veterinary Vaccines**

2:20  
**Discussion**  
Round table discussion including stakeholders of different species groups:  
Performance expectations / prioritization regarding veterinary vaccines (purity, safety, efficacy, availability, affordability, etc.)

10 minute presentations:  
- Swine, Scott Dee, Pipestone Veterinary Clinic  
- Bovine, Kenny Brock, Auburn University  
- Aquaculture, David Starling, Iowa State University  
- Companion animals, George Moore, Purdue University  
- Equine, Laurel Gershwin, University of California-Davis  
- Avian, Steve Roney, University of Georgia

3:30  
**Questions and discussion from audience**

**Meeting Summary**

4:00  
**Next Steps and Closing Remarks**  
Jim Roth, IICAB