
Draft Agenda
Iowa State University, Ames, Iowa
April 21 – 22, 2015

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 (CVB)

8:20 Overview of Potency Testing Policy Development
CVB Representative

8:50 Historical Perspective on Regulation of Potency of USDA Regulated Vaccines
CVB Representative
Hans Draayer, EDGE Veterinary Vaccines Consulting Group

9:50 Morning break

Issue 1: Product Efficacy and Potency

10:10 Minimum Protective Dose (MPD): How it is Established and What it Indicates
CVB Representative
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
CVB Representative
Richard Williams, Merial
2:15  **Pharmaceutical Shelf-Life Determination – Findings of the PQRI Stability Shelf-Life Working Group**  
James Schwenke, Consulting Statistician

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**  
Stability regulatory frame in EU (Jacques Léchenet, Merial)  
Stability assessment and definition of release specifications: an example with live vaccine (Vaughn Kubiak, Zoetis)  
Stability assessment and definition of release specifications: an example with inactivated vaccine (Wim Hesselink, MSD Animal Health)

5:20  **Questions and discussion from audience**

6:00  **Evening social hour with cash bar**

**Wednesday, April 22**

7:30  **Registration**

**Issue 3: Policy Considerations for Different Product Types**

8:00  **Product-Specific Considerations, e.g. Viral Vaccines (live, killed, vectored), Bacterins, Bacterial Extracts, Toxoids**  
CVB Representative  
Mark Zylstra, Boehringer Ingelheim

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
Kent McClure, Animal Health Institute
CVB Representative
EU Industry Representative

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
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, Speaker to be identified

3:30
Questions and discussion from audience

Meeting Summary

4:00
Next Steps
Jim Roth

4:15
Conclude meeting