Maintaining the Quality of Vaccines Through the Use of References Standards: Current Challenges and Future Opportunities

Library and Archives Canada
Ottawa, Canada

Re-scheduled
June 8-9, 2021

PROVISIONAL AGENDA – JULY 2020

Maria Baca-Estrada, Chair  Health Canada, Canada
Carmen Jungbäck, co-Chair  International Alliance for Biological Standardization (IABS), Germany
Ryan Brady  Merck, U.S.A.
Tara da Costa  Health Canada, Canada
Glenn Gifford  World Organisation for Animal Health, Canada
Rick Hill  International Alliance for Biological Standardization (IABS), U.S.A.
Robin Levis  Food & Drug Administration (FDA), U.S.A.
Laurent Mallet  European Directorate for the Quality of Medicines & HealthCare (EDQM), France
Catherine Milne  European Directorate for the Quality of Medicines & HealthCare (EDQM), France
Pieter Neels  International Alliance for Biological Standardization (IABS), Belgium
Todd Ranheim  Takeda Pharmaceuticals, U.S.A.
Philippe Sabot  International Alliance for Biological Standardization (IABS), France
Tim Schofield  International Alliance for Biological Standardization (IABS), U.S.A.
Dean Smith  Health Canada, Canada
Paul Stickings  National Institute for Biological Standards and Control (NIBSC), United Kingdom
Catrina Stirling  Zoetis, United Kingdom
Esther Werner  Paul-Ehrlich-Institut, Germany
Tuesday JUNE 8th

8:00 Registration
8:40 Welcome and introduction to the meeting

Session 1
Role of Reference Standards and Regulatory Expectations: Current Challenges
Chairs: Paul Stickings, NIBSC, United Kingdom; Sylvie Uhlrich, Sanofi Pasteur, France

9:00 Introductory presentation (historical perspective including brief overview of terminology)
Catherine Milne, EDQM, France

9:30 Regulatory expectations - veterinary vaccines
TBC

10:00 Regulatory expectation and OMCL experience – human vaccines
Gayle Pulle, Health Canada

10:30 Coffee break

11:00 Challenges when assessing multi component vaccine formulations: case study
Paul Stickings, NIBSC, United Kingdom

11:30 Manufacturers experience – veterinary vaccines
Catrina Stirling, Zoetis, United Kingdom

12:00 Manufacturers experience – human vaccines: Case studies
Delphine Collete, GSK

12:30 Lunch

13:30 Panel discussion

14:00 Introductory presentation
Tim Schofield, CMC Sciences, LLC, U.S.A.

Session 2
Principles and Practices: Standards Programs Part 1
Chairs: Tim Schofield, CMC Sciences, LLC, U.S.A.; Carmen Jungbäck, IABS, Germany

14:30 Design and analysis of collaborative studies
Peter Rigsby, NIBSC, United Kingdom

15:00 Principles and regulatory expectations for qualifications studies
Tong Wu, Health Canada

15:30 Coffee break
16:00  Manufacturers experience - veterinary vaccines  
      TBC

16:30  Manufacturers experience – human vaccines: Case studies  
      Sylvie Uhlrich / Emmanuelle Coppens (Sanofi)

17:00  Panel Discussion

17:30  End of Day 1

Wednesday JUNE 9th

Session 3
Principles and Practice: Standards Programs Part 2  
Chairs: Dean Smith, Health Canada; Catherine Milne, EDQM, France

8:30  Management of reference standards – an overview of the qualification process, stability  
      monitoring practices/requirements, and challenges in the veterinary field  
      Ryan Brady, Merck Animal Health

9:00  What to do if you determine your standard is unstable, or on strategies for qualification  
      David Laskey, PrecisionBioassay

9:30  TBD

10:00  TBD  
      Manish Gautam, Serum Institute of India

10:30  Coffee break

11:00  CEPI's Approach to Biological Standards and Assays – Starting Early rather than Late  
      Johan Holst, CEPI

11:30  Panel discussion

12:00  Lunch
      Breakout sessions

Session 4
Summary and Conclusions