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