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

Library and Archives Canada
Ottawa, Canada
June 8-9, 2020

PROVISIONAL AGENDA — FEBRUARY 2020

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Dean Smith
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Paul Stickings
National Institute for Biological Standards and Control (NIBSC), United Kingdom

Catrina Stirling
Zoetis, United Kingdom

Esther Werner
Paul-Ehrlich-Institut, Germany
MONDAY 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 Uhrlrich, 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

TUESDAY 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