Potency Testing of Veterinary Vaccines for Animals: The way from \textit{in vivo} to \textit{in vitro}

Langen, Germany, 01-03 December 2010

An international scientific workshop organised by

the Paul-Ehrlich-Institut (PEI)
the International Association for Biologicals (IABS)
the European Directorate for the Quality of Medicines (EDQM)

Scientific committee:

\textbf{Carmen Jungbäck}, PEI, Germany
\textbf{Marlies Halder}, EC/JRC/IHCP-ECVAM, Italy
\textbf{Wim Hesselink}, Intervet/Schering-Plough-IFAH, NL
\textbf{Rick Hill}, APHIS USDA, USA
\textbf{Jacques Lechenet}, Merial/IFAH, France
\textbf{David Mackay}, EMEA, UK
\textbf{Paul Midtlyng}, NVH, Norway
\textbf{Tim Miller}, Benchmarkbiolabs, USA
\textbf{Jim Roth}, ISU, USA
\textbf{Jean Marc Spieser}, EDQM, France
\textbf{William Stokes}, ICCVAM/NICEATM, USA

PROGRAMME
\textit{updated 04 October 2010}
Wednesday 01 December 2010

SESSION 1- Use of the 3R approach for potency (1)

Chairperson(s): Carmen Jungbäck and Jacques Lechenet

08:00 Registration
08:45 Opening
08:50 Welcome
Prof. Stefan Vieths / Vice-President of the PEI

09:05 Introduction speech (history, approaches, legal situation + political pressure, outlook, expectations)
Jean Marc Spieser / EDQM

09:25 Report from IABS meeting in Buenos Aires February 2010
Rodolfo Bellinzoni / Biogenesis Bago

9:45 Recent progress and future directions for the 3Rs in vaccine potency and safety testing: Conclusions and recommendations from the U.S. International Workshop, September 2010
William Stokes / NICEATM-ICCVAM

10:05 Discussion
10:20 Coffee break

10:50 Testing of vaccines against Rabies:
Replacement of challenge by serology: development of the test
Karin Duchow and Elisabeth Kamphuis / PEI

11:10 Testing of vaccines against Rabies:
Replacement of challenge by serology: collaborative study
Catherine Milne / EDQM

11:30 Testing of vaccines against Rabies:
Replacement of challenge by in vitro tests: considerations for development of the test
Donna Gatewood / APHIS-USDA

11:50 Testing of vaccines against Rabies:
Replacement of challenge by in vitro methods: comparison of test methods (RFFIT serology and in vitro)
Fabrizio de Mattia / Intervet/SPAH

12:10 Discussion
12:30 Lunch
SESSION 2 - Use of the 3R approach for potency (2)

Chairperson(s): Rodolfo Bellinzoni and Wim Hesselink

13:50 Erysipelas Vaccines: experience so far in development
  Jacques Lechenet / Merial

14:10 Erysipelas Vaccine: experience so far
  Elisabeth Balks / PEI

14:30 An antibody ELISA for potency testing of furunculosis (Aeromonas salmonicida subsp. Salmonicida) vaccines for Atlantic salmon: validation against experimental challenge tests
  Anne Berit Romstad and Paul J. Midtlyng / NVH

14:50 Clostridial Vaccines in animals: experience so far
  Keith Redhead / Intervet/SPAH

15:10 Discussion

15:25 Coffee break

15:55 The quantitative ELISA for inactivated Newcastle antigen: The development of the test system and the way to a Ph.Eur. in vitro potency test
  Hok Oei / CBG-MEB

16:15 The quantitative ELISA for inactivated Newcastle antigen: Experience report from official batch testing
  Andreas Motitschke / PEI

16:35 The quantitative ELISA for inactivated Newcastle antigen: Experience report from a manufacturer
  Fabrizio de Mattia / Intervet/SPAH

16:55 Discussion

17:10 End of the session

17:30 IABS meetings

19:30 Dinner
Thursday 02 December 2010

SESSION 3 – in vivo/ in vitro, a critical analysis

Chairperson(s): Tim Miller and Marlies Halder

08:30 The validation of potency tests, hurdles identified by EMA/CVMP/IWP
*Ralph Woodland / VMD*

08:50 The *in vivo* batch potency test: A critical analysis
*Jaap Woltjes / CBG-MEB*

09:10 Approach to *in vitro* potency testing when developing a new vaccine; is a parallel *in vivo* potency test necessary? (Important issue in R&D)
*Karen Brown / Pair O’docs Enterprises*

09:30 *In Vitro* Potency Tests: Challenges Encountered During Method Development (and Key Lessons)
*Vaughn Kubiak / Pfizer*

09:50 *In Vitro* Potency Tests: Challenges Encountered During Method Development, an researchers point of view
*Matthias König / Justus Liebig University Giessen*

10:10 Discussion

10:25 Coffee break

10:55 Successful Development and Validation of *in Vitro* replacement assays for veterinary vaccine potency tests: Lessons learned, a manufactures point of view
*Jean-Cassien de Foucauld / CEVA*

11:15 Successful Development and Validation of *in Vitro* replacement assays for veterinary vaccine potency tests: Lessons learned an authorities point of view
*Jodie Kulpa-Eddy / USDA Veterinary Services*

11:35 Established *in vitro* / consistency testing: need of retesting efficacy *in vivo*?
*Hervé Poulet / Merial*

11:55 AlphaLisa: improved sensitivity and increased speed for vaccine development
*Gregory Cosentino / PerkinElmer*

12:15 Discussion

12:30 Lunch
SESSION 4 – Consistency as an alternative to potency

Chairperson(s): Paul Midtlyng and William Stokes

13:50 Summary of the conclusions and recommendations of the EPAA/ECVAM workshop on the consistency approach for quality control of vaccines in Brussels January 2010
Marlies Halder / ECVAM

14:10 Consistency as tool for the final batch testing in GMP compliant production
Catrina Stirling / Pfizer

14:30 Consistency instead of potency. Introduction and acceptance of new methods, an example
Karin Duchow / PEI

14:50 Can the in vitro test assure potency? How relevant is it to add additional consistency parameters?
David Brake / Associates - DHS

15:10 Discussion

15:25 Coffee Break

15:55 Potential application of the consistency approach for vaccine potency testing
Juan Arciniega / US FDA, CBER

16:15 Appropriateness of in vitro potency tests or consistency tests for vaccine stability studies, stability of reference material
Mary Ann Pfannenstiel / Benchmark Biolabs

16:35 An in vitro antigen measure to replace an in vivo test, a proposal for a road map
Gergely Hamar / CEVA

16:55 Discussion

17:10 End of the session

18:30 Departure for dinner
Friday 03 December 2010

SESSION 5 - Conclusions and Recommendations

Chairperson(s) and Moderators: Jean Marc Spieser and Donna Gatewood

09:00  Cost analysis for in vitro potency testing, validation, and requalification. Justification for use of in vitro systems
       Marc Lee / Boehringer-Ingelheim

09:20  Reports from sessions

10:20  Coffee Break

10:50  Plenary discussion
       - Potency or consistency?
       - Detection of batches out of specifications
       - The need for standards and reference material
       - Impact assessment on changes
       - Validation of new methods against non validated established method
       - International acceptance
       - Comparison of “old” and “new” vaccines, data requirements
       - Animal testing as golden standard?
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12:30  Presentation and discussion of recommendations and possible follow up measures
       Carmen Jungbäck / PEI

13:00  Closing remarks

End of the meeting