

Potency Testing of Veterinary Vaccines for Animals: The way from *in vivo* to *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:

Carmen Jungbäck, PEI, Germany

Marlies Halder, EC/JRC/IHCP-ECVAM, Italy

Wim Hesselink, Intervet/Schering-Plough-IFAH, NL

Rick Hill, APHIS USDA, USA

Jacques Lechenet, Merial/IFAH, France

David Mackay, EMEA, UK

Paul Midtlyng, NVH, Norway

Tim Miller, Benchmarkbiolabs, USA

Jim Roth, ISU, USA

Jean Marc Spieser, EDQM, France

William Stokes, ICCVAM/NICEATM, USA

PROGRAMME

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
- 9:50 *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