

Viral Safety & Extraneous Agents Testing for Veterinary Vaccines

25- 27 October 2009- Annecy, France



IABS Veterinary Vaccines

Scientific Committee

Emmanuelle Charton, EDQM, France - **David A. Espeseth**, USA - **Wim Hesselink**, IFAH-Europe, Intervet/Schering-Plough Animal Health, the Netherlands - **Richard Hill**, USDA, USA - **Carmen Jungbäck**, Paul Ehrlich Institute, Germany - **Jacques Léchenet**, IFAH-Europe, Merial, France - **David Mackay**, EMEA, UK - **Paul Pierre Pastoret**, OIE, France - **Philippe Vannier**, AFSSA, France

Coordination : Dodet Bioscience, Lyon

PROGRAMME

updated 6 October 2009

SUNDAY 25 OCTOBER 2009

SESSION 1.- Opening : Rationale and background

Chairperson: Jacques Léchenet

- 16:15 Registration
- 17:00 Welcome address
Scope of the meeting
Daniel Gaudry, IABS and Jacques Léchenet, IFAH-Europe
- 17:15 Keynote lecture 1:
History of human and animal vaccine contaminations
Paul-Pierre Pastoret, OIE
- 17:50 Questions
- 17:55 Keynote lecture 2:
Current challenges in viral safety and extraneous agent testing
David Mackay, EMEA
- 18:30 Questions
- 18:35 End of the session
- Dinner

SESSION 2.1.- Current requirements: rationale and limitations

Chairperson: Philippe Vannier

- 09:00 Introduction by chairperson
- 09:05 VICH status and first steps
Wim Hesselink, Intervet/Schering-Plough Animal Health
- 09:15 Questions
- 09:20 Viral safety and requirements for extraneous agents testing: The Ph. Eur. approach
Lukas Bruckner, Institute of Virology & Immunoprophylaxis
- 09:35 Questions
- 09:40 Viral product testing regulations: The US approach
Donna Gatewood, USDA
- 09:55 Questions
- 10:00 Comparison of US and EU requirements for preclinical extraneous agent testing:
Examples
Sarah Sheridan, BioReliance
- 10:20 Questions
- 10:25 Testing for viral contaminants of veterinary vaccines in Hungary
Gabór Kulcsár, Institute for Veterinary Medicinal Products
- 10:45 Questions
- 10:50 Break
- 11:20 Extraneous agent testing in the USA: Application, results and interpretation
Donna Gatewood, USDA
- 11:40 Questions
- 11:45 Testing avian live virus vaccines for extraneous agents: How does it work in practice?
Hans-C. Philipp, Lohmann Tierzucht GmbH
- 12:05 Questions
- 12:10 Discussion
- 12:30 Lunch

SESSION 2.2.- Sources of potential contamination: Identification of real risk

Chairperson: Paul-Pierre Pastoret

- 14:00 Introduction by chairperson
- 14:05 Identification of viral risk – Example of human vaccines produced in insect cells
David Onions, BioReliance Corp, USA
- 14:25 Questions
- 14:30 The identification of viral risk in veterinary vaccines produced in insect cells
Christa Drexler, Intervet/Schering-Plough Animal Health
- 14:50 Questions
- 14:55 Traceability and control of sourcing of raw materials for vaccine manufacture
Laurence Faretra-Peysson, BD Diagnostics
- 15:15 Questions
- 15:20 Extraneous agents: What/where is the real risk?
Peer Lyng Frandsen, Danish Medicine Agency
- 15:40 Questions
- 15:45 Discussion
- 16:00 Break

SESSION 3.- Decontamination and inactivation treatments

Chairperson: David Mackay

- 16:30 Introduction by chairperson
- 16:35 Inactivation of active ingredient harvest as an example
Test for inactivation procedures and their validation
Franck Milward, Merial
- 16:50 Questions
- 16:55 Process validation: inactivation kinetics (key parameters to be studied – their validation)
Franck Milward, Merial
- 17:10 Questions
- 17:15 Decontamination and inactivating treatments: A regulatory perspective
Ralph Woodland, Veterinary Medicines Directorate, UK
- 17:30 Questions/Discussion
- 17:40 Low level contaminants (extraneous agents) in starting materials of animal origin
Jean-Claude Rouby, AFSSA
- 17:55 Questions

- 18:00 Example of starting material treatment/inactivation: Point of view from the industry
Gergely Hamar, CEVA
- 18:15 Questions
- 18:20 Discussion
- 18:30 End of session

TUESDAY 27 October 2009

SESSION 4.1.- Considerations of specific viral contaminants

Chairperson: Wim Hesselink

- 08:45 Introduction by chairperson
- 08:50 Extraneous agents testing for substrates of avian origin and viral vaccines for poultry:
Current provisions and proposals for future approaches
Carmen Jungbäck, Paul Ehrlich Institute
- 09:10 Questions
- 09:15 Risks linked to endogenous retroviruses: A general overview
Marie Dewannieux, Institut Gustave Roussy
- 09:30 Questions
- 09:35 Infectious endogenous retroviruses in live attenuated vaccines for companion animals
Takayuki Miyazawa, Kyoto University
- 09:50 Questions
- 09:55 Considerations on specific viral contaminants: example of a novel avian cell substrate
for the industrial production of viral vaccines
Majid Mehtali, Vivalis
- 10:10 Questions
- 10:15 Risks linked to Torque teno virus contamination
Gregory Nitzel, Pfizer
- 10:30 Questions
- 10:35 How is the problem of endogenous retroviruses handled in the US?
- 10:50 General discussion
- 11:00 Break

SESSION 4.2.- New tests: their contribution and limitations

Chairperson: Paul-Pierre Pastoret

- 11:30 Introduction by chairperson
- 11:35 New methods for detecting adventitious agents
David Onions, BioReliance Corp, USA
- 11:50 Questions
- 11:55 Purity testing of avian viral vaccines: Development, standardization and assessment of PCR systems
Hans-Peter Ottiger, Institute of Virology & Immunoprophylaxis
- 12:10 Questions
- 12:15 Purity testing of avian viral vaccines: Evaluation of PCR methods established by the Institute of Virology and Immunoprophylaxis and comparison with in vivo testing
Andreas Motitschke, Paul Ehrlich Institute
- 12:30 Questions
- 12:35 Discussion
- Risk analysis. What do we do with these tests?
- 13:00 Lunch

SESSION 5.- Round-Table

Chairperson: Carmen Jungbäck & Lukas Bruckner

- 14:30 Round-Table on Risk-Benefit Assessment
- Impact of controlling sourcing/implementation of GMP and QA system
 - Which tests for which steps?
 - o Testing of starting material including seeds
 - o Testing of viral contaminants during manufacturing
 - o Testing of final product
 - Which tests are necessary, could be reduced, replaced, deleted?
 - Are the current requirements still justified
- Paul-Pierre Pastoret, OIE; Rebecca Sheets, NIH, Jean-Marc Spieser, EDQM*
- 16:00 Break

SESSION 6.- Conclusions and Recommendations

Chairperson: Jacques Léchenet, with the chairperson of each session

- 16:30 Conclusions and recommendations
- 18:30 End of the meeting