



Novel *in-vitro* model as alternative to *in-vivo* toxoid vaccines testing: *Clostridium septicum* vaccine as proof of concept

Virtual Workshop Webinar Sessions on 9 & 10 March 2021

Programme

WEBINAR 1: Tuesday, 9 March 2021

13:00: *Technical Introduction by the EDQM, Council of Europe*

13:15: **Opening & Welcome addresses**

Laurent Mallet, Head of the Department of Biological Standardisation, OMCL Network & HealthCare (DBO), EDQM, Council of Europe

Session 1: Activities of study stakeholders in the field of 3Rs

Moderator: Michael Wierer, EDQM, Council of Europe

Rapporteur: Catherine Milne, EDQM, Council of Europe

13:30-13:40: European Directorate for the Quality of Medicines & HealthCare, Council of Europe

Catherine Lang, EDQM, Council of Europe

13:40-13:50: The European Partnership for Alternative Approaches to Animal testing (EPAA)

Irene Manou, EPAA

13:50-14:00: The European Union Reference Laboratory for alternatives to animal testing (EURL ECVAM) of the European Commission Joint Research Centre

Marlies Halder, JRC

Session 2: *Clostridium septicum* Vaccine Project (BSP130) Study aims and results

Moderator: Lukas Bruckner, Member Ph. Eur. Group of Experts
on Veterinary Vaccines and Sera (15V)

Rapporteur: Marie-Emmanuelle Behr-Gross, EDQM, Council of Europe

14:00-14:20: The Biological Standardisation Programme (BSP)

Catherine Milne, EDQM, Council of Europe

14:20-14:50: Outline of BSP130 Part 1 (Phase I & II)

Marie-Emmanuelle Behr-Gross, EDQM, Council of Europe (on behalf of Keith Redhead, Vaccines and Assay Consultancy Ltd, UK)

14:50-15:50: Outline of BSP130 Part 2 (Phase III)

- **Method Optimisation and their principals (TNE +, TCP)**

Balazs Dalmadi, CEVA-Phylaxia Veterinary Biologicals, Hungary

- **Statistics**

David Le Tallec, EDQM, Council of Europe

- **Results Overview**

Botond Siklodi, CEVA-Phylaxia Veterinary Biologicals, Hungary

15:50-16:10:



Break in the presentations

16:10-16:40:



Question & Answer Session

Session 3: Outcome of a Field Survey on Clostridium vaccines control

Moderator: Irene Manou, EPAA

Rapporteur: Marlies Halder, JRC

16:40-16:55: Feedback from BSP130 participants: experience and learnings

Marie-Emmanuelle Behr-Gross, EDQM, Council of Europe

16:55-17:10: Results of an Enquiry on alternative methods implementation by manufacturers

Catrina Stirling, EPAA

17:10:



Poll Session

17:30:



Question & Answer Session

18:00:

End of webinar 1

WEBINAR 2: Wednesday, 10 March 2021

13:30: *Technical Introduction by the EDQM, Council of Europe*

13:40: General Introduction

Laurent Mallet, Head of the Department of Biological Standardisation, OMCL Network & HealthCare (DBO), EDQM, Council of Europe

Session 4: Regulatory process

Moderator: Prof. Jean-Marc Person, Chair Ph. Eur. Group of Experts on Veterinary Vaccines and Sera (15V)

Rapporteur: Catherine Lang, EDQM, Council of Europe

13:50 -14:30: European Pharmacopoeia (Ph. Eur.) monographs overview and revision proposals

Achievements and issues for Ph. Eur. Group of Experts on Veterinary Vaccines and Sera (15V)

Lukas Bruckner, Expert and former Chair, Switzerland

Feedback from industry and way forward

David John, AnimalhealthEurope

14:30 -15:00: Regulators' perspective

- **Europe:** Esther Werner, Paul-Ehrlich-Institut (PEI)
- **USA:** Angela Walker, CVB, Animal and Plant Health Inspection Service (APHIS)

15:00-15:30:  *Question & Answer Session*

15:30-15:45:  *Break in the presentations*

Session 5: Potential application of the Approach to other Toxoid Vaccines - Update on Vac2vac Projects.

Moderator: Elisabeth Balks, PEI, Germany

Rapporteur: Marie-Emmanuelle Behr-Gross, EDQM, Council of Europe

15:45-16:05: Experience in extending the approach of cell-based TCP and MLD assays to *Clostridium perfringens* vaccines

Arjen Sloots, Institute for Translational Vaccinology (Intravacc), The Netherlands

16:05-16:35: Perspectives for extending the approach to other toxoid vaccines target vaccines

Mohammad Daas, MSD Animal Health, UK

16:35-16:50:



Poll Session

16:50-17:10:



Question & Answer Session

Session 6: Concluding Session

Moderators: Esther Werner, PEI and Laurent Mallet, EDQM, Council of Europe

Rapporteurs: Lukas Bruckner (Expert), Marlies Halder (JRC), David John (AnimalhealthEurope) and Catrina Stirling (EPAA)

17:10-17:30: Summary of the workshop sessions from the rapporteurs

17:30-17:50:



Question & Answer Session with the Members of the Scientific Committee and Speakers

17:50: Concluding Remarks

Esther Werner, Paul-Ehrlich-Institut (PEI)

Laurent Mallet, EDQM, Council of Europe

18:00: *End of webinar 2*



Members of the Scientific Committee

Marie-Emmanuelle Behr-Gross, EDQM, Council of Europe
Lukas Bruckner, Member of Ph. Eur. Group of Experts 15V
Balazs Dalmadi, CEVA-Phylaxia Veterinary Biologicals, Hungary
Marlies Halder, JRC
David John, AnimalhealthEurope
Laszlo Kiss, CEVA- Phylaxia Veterinary Biologicals Co. Ltd., Hungary
Catherine Lang, EDQM, Council of Europe
David LeTallec, EDQM, Council of Europe
Laurent Mallet, EDQM, Council of Europe
Irene Manou, EPAA
Catherine Milne, EDQM, Council of Europe
Keith Redhead, Vaccines and Assay Consultancy Ltd, UK
Botond Siklodi, CEVA-Phylaxia Veterinary Biologicals, Hungary
Natalia Sinitskaya, EDQM, Council of Europe
Catrina Stirling, EPAA
Esther Werner, PEI
Michael Wierer, EDQM, Council of Europe

Organising Committee

Marie-Emmanuelle Behr-Gross, EDQM, Council of Europe
Fiona Gilchrist, EDQM, Council of Europe
Marlies Halder, JRC
Irene Manou, EPAA
Laurence Montard, EDQM, Council of Europe
Natalia Sinitskaya, EDQM, Council of Europe
Clare Williams, EDQM, Council of Europe
Sally Woodward, EDQM, Council of Europe
Zvonimir Zvonar, EPAA