

AUTOGENOUS VACCINES: Quality of production and movement in a common market

Ludwig Maximilians University (LMU)
Pettenkoferstrasse 12
80336 München

A Hybrid Meeting



**Munich, Germany
September 14 - 16, 2021**

Scientific committee:

- **Carmen Jungbäck**, International Alliance for Biological Standardization – Europe (IABS-EU), Germany
- **Klaus-Peter Behr**, Anicon, Germany
- **Gerfried Zeller**, European Manufactures of Autogenous Vaccines & Sera (EMAV), Germany
- **Peter Schmid**, CEVA, Germany
- **Dusan Palic**, Ludwig Maximilians Univeristät (LMU), Germany
- **Vaughn Kubiak**, International Alliance for Biological Standardization (IABS), France
- **Jiri Bures**, USKVBL, Czech Republic
- **Mariette Salery**, French Agency for Food, Environmental and Occupational Health & Safety (ANSES-ANMV), France
- **Jason Todd**, Veterinary Medicines Directorate (VMD), United Kingdom
- **Nathalie Vassallo**, LABOCEA, France
- **Maarten de Gussem**, Poulpharm, Belgium
- **Iska Lehmann**, Lower Saxony State Office for Consumer Protection and Food Safety (LAVES), Germany
- **Santiago Cabaleiro**, Aquaculture Cluster of Galicia (CETGA), Spain

For Veterinarians located in Germany the ATF (Akademie für Tierärztliche Fortbildung) granted 14 hours of training.

TUESDAY 14th OF SEPTEMBER, 2021

- 13:00** Registration & Virtual connection
- 14:00** Opening – *Carmen Jungbaeck, IABS, Germany*
- 14:05** Welcome – Reinhard Straubinger, Dean – Faculty of Veterinary Medicine LMU

SESSION 1: EXPECTATIONS FROM DIFFERENT STAKEHOLDERS

Moderators: Santiago Cabaleiro, Vaughn Kubiak

- 14:30** The EMAV proposal for harmonization of GMP for autogenous vaccines - *Klaus-Peter Behr, EMAV, Germany*
- 14:45** Expectations from different stakeholders – german national authority – *Dr. Dietrich Rassow, CVO, BMELV, Germany*
- 15:00** Feedback and contribution from French inspectorate perspective – *Gregory Verdier, ANSES-ANMV, France*
- 15:15** ***Break***
- 15:25** Autogenous Vaccines and regulation 2019/6 – *Mariette Salery, ANSES-ANMV, France*
- 15:40** Expectations from EMAV-manufacturer's perspective – *Maarten De Gussem – Poulpharm, Belgium*
- 15:55** ***Coffee Break***
- 16:25** Animal Health Europe Views – *David John, AHE, Belgium*
- 16:40** Aquaculture and the use of autogenous vaccines for fishes – *Jordi Lopez Ramon, FEADSA, Spain*
- 17:10** Autogenous Vaccines: an insight of their use by French pig practitioners – *Florian Voisin, HYOVET, France*
- 17:25** Veterinary Use of Autogenous Vaccines: opportunities and challenges of the EU Medicines Regulation – *Nancy de Briyne, FVE, EU*
- 17:40** Discussion
- 18:10** **End of Day 1**

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WEDNESDAY 15th OF SEPTEMBER, 2021

SESSION 2: STARTING MATERIALS + SEEDS

Moderators: Gerfried Zeller, Jason Todd

- 8:30** Starting Materials and Seeds – National Authority views – *Rory Cooney, VMD, United Kingdom*
- 8:50** Starting materials and seeds – *Brigitte Othmar-Vielitz, EMAV, Germany*
- 9:10** Manufacturing of fish viral autogenous Vaccines (case study: ISKNV) – *Panos Christofilogiannis, Aquatreck, Spain*
- 9:30** **Break**
- 9:40** Starting materials and Seeds – Further considerations – Bacterial Autogenous Vaccines – *Jean de Foucauld, Biovac-CEVA, France*
- 10:00** Manufacturer Bacterial Aquatic – *Santiago Cabaleiro, CTGA, Spain*
- 10:20** Addressing autogenous vaccine needs with adjuvant technologies – *Sebastien Deville, Airliquide, France*
- 10:40** Discussion
- 11:10** **Coffee Break**

SESSION 3: PREMISES + PERSONNEL

Moderators: Maarten De Gussem, Dusan Palic

- 11:40** GMP Requirements for personal and premises in the autogenous vaccines production from the point of view of a supervisory authority – *Iska Lehmann – LAVES, Germany*
- 12:10** Inactivated autogenous vaccines in Hungary - Manufacturing and use – *Ernö Horvath, NEBIH, Hungary*
- 12:40** **Lunch Break**
- 14:00** Premises for Autogenous Vaccine Production – *Wiebke Bielenberg, Klaus-Peter Behr – ANICON, Germany*
- 14:30** Autogenous Vaccines: Monitoring of premises and Personnel from perspective of the Industry – *Ewald Van Kuppeveld, RIPAC, Germany*
- 15:00** Discussion

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15:30 **Coffee Break**

SESSION 4: MANUFACTURE + FINAL BATCH CONTROL

Moderators: Santiago Cabaleiro, Klaus-Peter Behr

- 16:00** Requirements for the manufacture, control, prescription and use of veterinary medicinal products autogenous vaccines in the Czech Republic– *Petra Mullerova, USKVBL, Czech Republic*
- 16:20** Autogenous Vaccine Production: Challenges and Opportunities – *Ynte Schukken, Deventer, Netherlands*
- 16:40** **Break**
- 16:50** Manufacturer & Final Batch Control, Bacterial Vaccines – *Dietmar Katinger, BS-Immun, Austria*
- 17:10** Manufacturing and control of viral vaccines: Specific challenges for autogenous products – *Annie Sigognault-Flochlay, FILAVIE, France*
- 17:30** Case of new, recently approved autogenous vaccines facility: what are the challenges in terms of design, engineering and equipment to fulfill GMP regulation? – *Alain Schrumpf & Laurent Drouet - CEVA, France*
- 17:50** Discussion
- 18:20** **End of Day 2**

THURSDAY 16th OF SEPTEMBER, 2021

SESSION 5: USE OF VACCINES, IMPORT, EXPORT, SURVEILLANCE

Moderators: Joris Vandeputte, Peter Schmid

- 9:00** On the use of autogenous vaccines – the perspective of the standing committee for veterinary vaccines – *Max Bastian, FLI, Germany*
- 9:20** Current situation on the Autogenous Vaccines in Belgium: Challenges and the way forwards – *Dries Minne, Belgium*
- 9:40** Use and authorization of autogenous veterinary vaccines in Spain – *Rosario Bullido, Spain*
- 10:00** Discussion
- 10:30** **Coffee Break**

SESSION 6: SUMMARY AND CONCLUSIONS

Moderators: Vaughn Kubiak, Klaus-Peter Behr

- 11:00** Summary of the Sessions and the Discussions – *Moderators of the sessions*
- 11:45** Conclusions and Recommendations and Plenary Discussion – *All participants*
- 12:45** Closing Remarks – *Joris Vandeputte, IABS-EU*
- 13:00** **End of the Conference**