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International Alliance for Biological Standardization

EMAV

Autogenous Vaccines : Quality of Production and Movement in a Common Market

September 14-16, 2021

Ludwig Maximilian University
MUNICH - GERMANY

An IABS-EU & EMAV Meeting

LMU LUDWIG-MAXIMILIANS-UNIVERSITÄT MÜNCHEN

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About the Conference

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There is a lack of vaccines ad us vet, as the existing licensing procedures within EU are demanding concerning the scientific requirements, the length, costs and complexity of procedures. Therefore, vaccines manufacturers tend to focus on the licensing and manufacture of products that have defined development pathways, demonstrated veterinary need, and reasonable expectations for a return on investment. As a consequence the market for autogenous vaccines to meet "niche" customer needs increase despite a minimally-regulated situation, especially in terms of manufacturing quality. There is no mutual recognition of GMP or GMP like certificates. Vaccination in general and in particular autogenous vaccines contribute to a better use and a global reduction of antibiotics use in livestock productions.

There are no harmonised provisions concerning the manufacture and control of autogenous vaccines within EU. The authorities seem to pay less attention as well the movement of vaccines or vaccinated animals from one country to another one.

First attempt is to harmonise some requirements, based on the CMDv paper on this item and in the purpose of the revision of the veterinary medicinal product legislation in EU.

The meeting is intended to initiate productive conversations with manufacturers, competent authorities and users to develop a draft proposal how to form a common market which will improve overall disease control in the community, especially for diseases that suffer from a lack of conventionally-authorised products. The proposal should support the efforts of the French and Czech EU-Presidencies in 2022.

Key items will be: GMP /GMP-like requirements, mutual recognition of inspections, import and export of autogenous vaccines, relevance and impact on diagnostics and the information on vaccinated animals whenever they are moved to allow an epidemiological surveillance.

Scientific and Organizing Committee

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Carmen Jungbäck - IABS-EU, DE

Klaus-Peter Behr - Anicon, DE

Gerfried Zeller - EMAV, DE

Peter Schmid - CEVA, DE

Dusan Palic - LMU, DE

Vaughn Kubiak - IABS, FR

Jiri Bures - USKVBL, CZ

Mariette Salery - ANSES-ANMV, FR

Jason Todd - VMD, UK

Nathalie Vassallo - LABOCEA, FR

Maarten de Gussem - Poulpharm, BE

Iska Lehmann - LAVES, DE

Santiago Cabaleiro - CETGA, ES

Scientific Program

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Tuesday 14th of September, 2021

Ludwig Maximilians University (LMU) - A Hybrid Meeting

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

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Tuesday 14th of September, 2021

Ludwig Maximilians University (LMU) - A Hybrid Meeting

Session 1: Expectations from Different Stakeholders

Moderators: Santiago Cabaleiro, Vaughn Kubiak

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

Ludwig Maximilians University (LMU) - A Hybrid Meeting

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) – **Dr. 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

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Wednesday 15th of September, 2021

Ludwig Maximilians University (LMU) - A Hybrid Meeting

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	Manufacturer Bacteria : Monitoring of premises and Personnel from perspective of the Industry – **Ewald Van Kuppeveld, RIPAC, Germany**
15:00	Discussion
15:30	Coffee Break

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Wednesday 15th of September, 2021

Ludwig Maximilians University (LMU) - A Hybrid Meeting

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 and Laurent Drouet - CEVA, France**
17:50	Discussion
18:20	End of Day 2

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Thursday 16th of September, 2021

Ludwig Maximilians University (LMU) - A Hybrid Meeting

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 speakers and moderators**
12:45	Closing Remarks – **Joris Vandeputte, IABS-EU, Belgium**
13:00	End of the Conference

Upcoming IABS Conferences and Workshops

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Accelerating Drug Development: How QbD, Regulatory Partnerships, and Pandemic Learning Can Further Expedite Meeting Patient Needs

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Maintening the Quality of Vaccines through the Use of References Standards Current Challenges and Future Opportunities

June, 2022

Cross Learning Experience Human and Animal Vaccine Licensure based on Technology Platforms

Max Bastian

On the use of autogenous vaccines – the perspective of the standing committee for veterinary vaccines

Secretary of the Standing Committee on Veterinary Vaccines
Greifswald – Insel Riems

Background: The Standing Committee on Veterinary Vaccines (StIKo Vet) is a commission of veterinary experts that issues guidelines on the use of veterinary vaccines and gives advice to the German Federal Government on veterinary immune prophylaxis. The evaluation of autogenous vaccines is part of the mandate of the StIKo Vet as it is laid down through the German Animal Health Law. The committee is hosted by the Friedrich-Loeffler-Institut, the Federal Research Institute for Animal Health.

Issue: In April 2020 the StIKo Vet has published a guidance paper on the use of autogenous vaccines. In this paper legal premises and practical aspects of their use are discussed. Although licensed vaccines must be preferred, wherever they are available, it is appreciated that autogenous vaccines can help to fulfill medical needs in cases where licensed vaccines are unavailable. This is particularly but not exclusively true for bacterial pathogens that display a high variety of serotypes. In contrast to licensed vaccines that undergo a thorough authorization procedure, autogenous vaccines by nature are not tested for their efficiency and safety. This poses a particular responsibility on the manufacturer e.g. to choose the right isolate and to adhere to optimal manufacturing practices. At the same time the practitioner has to observe precaution measures when administering the products and has to monitor its effect.

Conclusions: The StIKo Vet is aware that autogenous vaccines can be an important tool in the veterinary practice for the prevention of infectious diseases. At the same time the committee emphasizes the importance of a strict control of the production and the use of autogenous vaccines. From the perspective of the StIKo Vet, in the delegated acts on Regulation (EU) 2019/06 that are concerned with autogenous vaccines the role of the competent authorities controlling manufacturer and practitioners should be strengthened.

Wiebke Bielenberg

Wiebke Bielenberg

Premises for Autogenous Vaccine Production

Head of Production, Qualified Person - AniCon Labor GmbH
Höltinghausen - Germany

REGULATION (EU) 2019/6 on veterinary medicinal products defines general conditions for the standardisation and harmonisation of the manufacturing and use of autogenous vaccines in future. An important basis for the manufacturing is the production environment which should be safe and controlled.
The manufacturing premises must provide conditions ensuring the required quality of the product.
Suitable environmental conditions must be ensured on a risk basis for each facility.
Basic requirements are eg that there is a directional air flow from clean to unclean areas which additionally prevents potentially contaminated air from production rooms from reaching surrounding areas. The air in production facilities, airlocks and changing rooms should be filtrated (HEPA).
The layout of the premises should be appropiate and correspond to the sequence of the operations and to the required cleanliness levels.
A principal difference in autogenous vaccines compared to licensed ones lies in the parallel production of different products – here each manufacturer has to define appropiate risk-based measures to prevent mix-up and cross-contamination.

The future european GMP legislation for Autogenous Vaccines will fulfil the need for standardised specifications on requirements for buildings, rooms and production conditions.
The final implementation of the requirements by the manufacturers must take into account the respective production setting since autogenous vaccines exhibit a variety of products - including very different production processes and antigens.
Each manufacturer has to document an appropriate risk assessment for his list of antigens – with special regard to viral antigens, processes and premises to control the hygienic production conditions.
All measures to prevent (cross-)contamination should be commensurate with the risks and ensure a secure and clean production environment.
The elaborated proposals of the EMAV on the future environmental conditions of the production of autogenous vaccines against viral infections are described and the deviations from the conditions for the production of licensed vaccines are explained and justified.

Rosario Bullido

Use and authorization of autogenous veterinary vaccines in Spain

Head of Veterinary Biologicals - Immunologiscals Assessment Unit.
Veterinary Medicines Department
Madrid - Spain

Summary: The speech focuses on present and future legislation applicable (currently under discussion) in Spain for autogenous vaccines, particularly dealing with:
- Definitions
- Authorisation and use
- Different competent authorities (Autonomous Regions, Ministry of Agriculture, Spanish Agency for Medicines and Medical Devices) involved in this authorization and control, and
- Information about contact points and manufacturers.

Conclusions: To be discussed during the meeting.
All the implied parts, including regulators and stakeholders expect to reach an improvement in relation with current situation. This needs an effort from all the interested parts in search of a higher quality and reliability of the autogenous vaccines. In my personal point of view I believe that the inclusion of the following issues in application of the new EU veterinary medicines Regulation and the future specific Spanish legislation will contribute in this process, specifically:
- inclusion of flexibility with the "epidemiological link"
- improve the quality and control of these medicines,
- A more fluid relationship between the different competent authorities involved is needed for authorization, use control and monitoring of autogenous vaccines.
And I also expect that better feed-back from manufacturers and users will be given in the future, at least with the Veterinary Department of the AEMPS

Santiago Cabaleiro

Manufacturer Bacterial Aquatic

Director - Centro Tecnológico del Cluster de la Acuicultura
Ribeira - Spain

One of the most useful tools available to veterinarians and production managers are autovaccines and vaccines. Since the beginning of the expansion of fish aquaculture in the second half of the 20th century, research has been carried out in the development of vaccines for different viral and bacterial pathogens. Parallel to the use of vaccines, veterinarians have had to draw on to the use of autovaccines because of the decrease in the efficacy of vaccines against bacterial pathogens. It is a very frequent fact, and the reasons are multiple, being something that is repeated all over the world, both for continental and marine aquaculture. The adaptation of bacteria to each environment with changing physical and chemical parameters for each location becomes a challenge for aquaculture professionals and this is where autovaccines are most useful. Autovaccines can be monovalent, bivalent or polyvalent, the autovaccine laboratory will advise on the best available technology and the side effects that each option may have in order to offer an immunological product with the maximum guarantees in safety and efficacy in the shortest possible time an manufactured with GMP adapted autovaccine manufacturing processes. When a veterinarian contacts the autovaccine manufacturing laboratory, an internal procedure is triggered with the aim of manufacturing an autovaccine against the pathogen or pathogens that cause mortality in production.

The pathogens of a farm can be always the same, so if this is the current situation a previous isolate from that farm can be used for the production of the autovaccine, another situation for technicians is face an emerging pathogen, so the strategy for the elaboration of the autovaccine it's complete different and includes; obtaining an isolate from fish, identify the bacteria of each isolate and select the bacteria that potentially causing the disease in base on the information about the target fish species and the location of the farm. It is very important for the veterinarians identify the main pathogen that cause the outbreak, and which are the secondary ones, with all these data the laboratory will manufacture a safe and effective autovaccine.

Panos Christofilogiannis

Panos Christofilogiannis

Manufacturing of fish viral autogenous Vaccines (case study: ISKNV)

Director - Aquatreck Animal Health
Pontevedra - Spain

Nile tilapia is the most widely cultured fish species globally (farmed in 140 countries, global production in 2021 is estimated at 7.29m metric tons) driven by its good feed conversion, fast growth, high reproduction, and ease of production providing food security and prosperity to rural communities. Nile tilapia production in Ghana reached 53,000 tonnes in 2017 with more than 90% of the production derived from high stocking density floating cage systems in Lake Volta.

In 2019 unusual patterns of very high mortality (>50% production) were reported in intensive tilapia cage culture in Lake Volta in Ghana. Frozen spleen and kidney tissue or whole fry were received and analyzed. Samples were homogenized in 1:10 w/v cell culture transport medium (L-15 plus 1% antibiotic–antimycotic solution). Homogenate was clarified by centrifugation & the supernatant filtered, the sample filtrate was inoculated at 1:100 and 1:1,000 dilutions onto GF, BF-2 and E-11 cells in 24-well cell culture plates and incubated at 25°C. Cells were observed for 5-10 days for cytopathic effect (CPE) by Inverted microscope. A further 2 consecutive blind passages were performed on cell supernatant at 7 days post infection. ISKNV PCR was also performed on original isolate and all three passages to confirm identity. Iridoviruses are large icosahedral cytoplasmic double-stranded DNA viruses, which can infect a wide range of hosts, including invertebrates and poikilothermic vertebrates. Infectious spleen and kidney necrosis virus (ISKNV) is a member of the genus Megalocytivirus and causes disease in a range of freshwater and marine fish species. Vaccination as a control strategy was used effectively to control ISKNV in mandarin fish using inactivated whole cell vaccines.

Rapid development of autogenous vaccine based on the direct use of the strain of ISKNV from Lake Volta tilapia farm was possible for the first time. The process followed, and the challenges encountered in the production of this autogenous viral vaccine is described.

Rory Conney

Starting Materials and Seeds – National Authority view

Head of Biologicals - Veterinary Medicines Directorate (VMD)
Addlestone, Surrey - United Kingdom

The Veterinary Medicines Directorate (VMD) is the UK national competent authority for the regulation of veterinary medicinal products. The UK has a well-established national legislative framework covering manufacture of inactivated autogenous veterinary vaccines with legislative, authorisation, GMP inspection, batch release and pharmacovigilance activities all within the VMD. Autogenous Vaccine Authorisations (AVAs) covering manufacture of bacterial and viral autogenous vaccines have been granted under the current scheme since 2006, with manufacturers located both in the UK and the EU.

Use of inactivated autogenous vaccines is increasing and cross-border movement of vaccinated animals is common practice. Guidance and common standards on the minimum quality standards required for the preparation, manufacture and control of inactivated autogenous vaccines is required.

Session 2 of the meeting focuses on starting materials and seeds and this opening presentation is a view from a national regulatory authority. Starting materials means all components used in the production of the inactivated autogenous vaccine including active substances/seed materials, culture media, adjuvants, other excipients and primary packaging. We will discuss the minimum requirements currently expected for starting materials and seeds for inactivated autogenous vaccines, reflect on experiences to date – what works well and where there are areas for improvement, and recommendations for the future.

Sebastien Deville

Addressing autogenous vaccine needs with adjuvant technologies

Europe Business Development & Open Innovation Manager Vaccine Adjuvant Market - SEPPIC
Paris - France

Background:
Autogenous veterinary vaccines are increasingly used to address critical vaccination needs and contribute to a global reduction of antibiotics used in livestock productions. They are essential to fill the gap wherever licensed vaccines are not available. They have specific requirements in terms of safety, efficacy, development and need to be quickly delivered for animal administration in order to reduce disease occurrences. Autogenous vaccines are produced from bacterial and/or viral cultures from farms, inactivated antigens, that often require adjuvants to trigger an adequate immune response.

Materials & Methods:
In order to select adequate Montanide™ technologies for autogenous vaccines we have evaluated them according to the following items: vaccine formulation, ease of handling and vaccine stability improvement with regards to destabilising antigenic medium. Field trial results gathered in different species help to select technologies to be preferred with regards to safety and immune protection.

Results:
The best galenic performance was obtained with oil adjuvants MontanideTM ISA 28R VG and ISA 71R VG. These adjuvants allowed the formulation of stable emulsions even with antigen destabilising media.

Abstract

Sebastien Deville

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Montanide™ ISA 71R VG is largely used for water in oil emulsified vaccines for poultry and has proven its safety and efficacy in many field trials. For poultry vaccination, water in oil adjuvant Montanide™ ISA 78 VG has also been identified as a good candidate, in particular when a fast onset of immunity is required.
For swine vaccination, the oil in water emulsified vaccines with Montanide™ ISA 28R VG have demonstrated very good tolerance with excellent protection, compatible with a use in autogenous vaccines.
Finally, for fish vaccination, Montanide™ GEL 02 has shown the best performance in terms of safety and efficacy to vaccinate Nile Tilapia against Streptococcus agalactiae.

Conclusions:
The large portfolio of Montanide™ technologies is able to offer adequate adjuvant for each animal species in line with autogenous vaccine requirements. Different adjuvants for vaccines coming into emulsion or aqueous forms have been identified to be in line with efficacy, safety and formulation specific needs.

Nancy De Briyne

Veterinary Use of Autogenous Vaccines: opportunities and challenges of the EU Medicines Regulation

Executive Director of the Federation of Veterinarians of Europe (FVE)
Ghent - Belgium

The Federation of Veterinarians of Europe (FVE) is an umbrella body for veterinary associations from 39 European Countries. Through our Sections, we represent veterinarians working in different fields of the profession, such as veterinary practitioners (UEVP), state officers (EASVO), food safety and veterinary public health (UEVH) and veterinarians working in education, research and industry (EVERI).

FVE followed the long process of the development of the new Regulations on Veterinary Medicines (EU) 2019/6 and Medicated Feed (EU) 2019/4, which started in 2010. The availability of veterinary medicines, including vaccines, is a longstanding problem in veterinary medicine due to the need for treatment of different animal species and indications. The new Regulation includes several provisions to enhance availability of veterinary medicines, including (autogenous) vaccines. Autogenous vaccines can play a role here to close gaps in preventing certain diseases when licensed vaccines are not be available.

FVE specifically looked at the use of autogenous vaccines in different species in order to prevent diseases and reduce the need to treat with antimicrobials, see annex to the EMA EFSA joint opinion on reducing the use of antimicrobial agents in animal husbandry (RONAFA opinion).

FVE also looked at autogenous vaccines in relation to the treatment for aquatic animals in the FishMedPlus Coalition, a wide coalition of aquaculture actors, with as aim to improve the availability of authorised medicines, including vaccines, for aquatic species in the EU and EFTA countries.

Abstract

Nancy De Briyne

2/2

References:

- FVE, Antimicrobial use in food-producing animals, Annex to the RONAFA opinion, 2015, https://www.ema.europa.eu/en/documents/report/annex-replies-efsa/ema-questions-use-antimicrobials-food-producing-animals-eu-possible-measures-reduce-antimicrobial_en.pdf

- FishMedPlusCoalition, Report on barriers and solutions, 2019, https://www.researchgate.net/publication/333401967_This_is_the_second_report_of_the_FishMedPlus_Coalition_the_first_report_was_on_the_need_for_specific_medicinal_products_and_vaccines_for_farmed_fish_This_second_report_deals_with_barriers_and_solution

Jean De Foucauld

Starting materials and Seeds – Further considerations – Bacterial Autogenous Vaccines

Senior Biology Expert - Ceva Santé Animale
Libourne - France

The success of an autogenous vaccine is based on the right selection of the micro-organism responsible for the disease in the animal, in the farm or in the epidemiological unit, from which an active ingredient is made and formulated as a vaccine. The role the starting materials in this process, is key; sourcing, testing of the starting materials must ensure vaccine quality, in matter of epidemiological relevance (e.g. identity test of the vaccine strain), of extraneous agent risk and of BSE/TSE compliance. Other considerations like optimal antigen growth criteria, GMP requirements are to be considered.

The presentation discusses those aspects, with a specific focus on bacterial vaccines.

Maarten De Gussem

Expectations from EMAV-manufacturer's perspective

Managing Director - Poulpharm
Izegem - Belgium

BACKGROUND—EMAV, the European Manufacturer's of Autogenous Vaccines representation body, has as mission to help developing future GMP standards in a way to combine securing safety and availability of autogenous vaccines, even for very small number of animal(s). To meet these objectives, a scientific working group has been working on a EMAV Proposal for a dedicated EU-GMP-Annex for Autogenous vaccines, passed by the EMAV membership unanimously and presented at the "2021 Munich IABS-EU EMAV Meeting" (https://www.emav.be/position-papers).

CHALLENGE—Understanding the needs of veterinarians in application of autogenous vaccines in order to reduce use of antibiotics in companion and production animals, protection of animal welfare and endangered species, supporting global food supply chains in a sustainable and economic way while protecting the environment is key in order to develop a GMP standard that guarantees consumer protection due to harmonized quality standards.

APPROACH BEING TAKEN— "Recommendations for the manufacture, control and use of inactivated autogenous veterinary vaccines within the EEA", the CMDv 2017 position paper, has been used as a starting point in a process where different manufacturers from a vast range of member states shared concerns, positions and background. These discussions have led to a position paper that is supposed to inspire other stakeholders to have similar reflections in order to come to a consensus on GMP standard for Autogenous Vaccines.

CONCLUSIONS—EMAV will, based on the feedback on the presented proposal, understand the needs from different stakeholders (animal owners, veterinarians, competent authorities), in support of defining critical points in order to reach a stakeholder consensus on a GMP-EU standard. We expect a common statement at the end of the conference compiling consensus standards and critical points.

Laurent Drouet & Alain Schrumpf

Case of new, recently approved autogenous vaccines facility: what are the challenges in terms of design, engineering and equipment to fulfill GMP regulation?

QP Ceva Biovac
Beaucouzé - France

Case of a new, recently approved autogenous vaccine facility:
what are the challenges in terms of design, engineering and equipment to fulfill GMP regulation?

The project has been started in 2017 due to an increase of the autogenous vaccine demand which saturated the prior facility. The discussion on EU regulation was on going with the possibility to have a GMP level required for production. Since 2009, France has a specific GMP regulation for autogenous vaccine manufacturing.
Ceva Biovac decided to build a full GMP site while keeping the agility necessary for a production of autogenous vaccines.

The site was designed following the GMP principles, the equipment are adapted to the flow of production and the level of production in terms of number of batches and batch size. The monitoring has been designed to perform a control of all productions areas and to guarantee the good assurance of sterility level of all clean room. Documentation has been updated or created to keep all information available as requested by the GMPs.
Qualifications of all equipment have been started as early as possible (design qualifications) and performed to comply with the GMP regulation before the inspection of the French authorities.

The main challenges points versus GMP are:

- multi product facility,
- adaptation to a high number of small manual manipulations
- manufacturing software validation.

Abstract

Laurent Drouet

2/2

Risk analysis were carried out before production started. Appropriate measures to prevent mix-up or cross-contamination risk were implemented. This process was validated by the French authorities. The new facility has received a GMP certificate in July 2021.

Erno Horvath

Inactivated autogenous vaccines in Hungary - Manufacturing and use

Head of Inspectorate - National Food Chain Safety Office
Directorate for Veterinary Medicinal Products
Budapest - Hungary

Presentation is about the conditions of manufacturing and use of inactivated autogenous vaccines in Hungary. Legal requirements have been since 2012. Authorisation has two stages first for manufacturing and second for use. GMP certificate is not required for manufacturing. GMP like production is enough. Manufacturing authorisation in itself is accepted if an EEA national authority issued it. However, in the Hungarian authorisation the number of the agents are generally less than in the original authorisation. The most important to ensure that the inactivated autogenous vaccines are properly inactivated, free from extraneous agents and sterile. Most of the manufacturing authorisation i.e. six from eight are for bacterial vaccines. There are only three viruses are authorised for inactivated autogenous vaccine production: cattle papillomavirus, avian adenovirus and goose polyomavirus. A permission for use is submitted for every batch after release tests including safety test. The number of permissions for use has increased from 19 in 2015 to 160 in 2020. Special production is allowed for goose polyoma vaccine where the use is valid for the whole country and there is an efficacy test for it. Inactivated autogenous vaccines are good complements for vaccines with marketing authorisation especially at the minor species and when the efficacy is not satisfactory in case of serovariants.

Dietmar Katinger

Manufacturer & Final Batch Control, Bacterial Vaccines

CEO - Polymun Scientific Immunbiologische Forschung GmbH
Klosterneuburg - Austria

The production of autogenous vaccine for veterinary use differs markedly from the large-scale production of licensed veterinary vaccines. In addition, the time for the production requires different procedures. Finally, the narrow scope of application of an individual autogenous vaccine lot is resulting in a clearly reduced risk profile. The presentation will highlight the resulting difference in requirements for production guidelines.

Iska Lehmann

GMP Requirements for personal and premises in the autogenous vaccines production from the point of view of a supervisory authority

GMP - requirements for personnel and premises in the autogenous vaccines production from the point of view of a supervisory authority
Hannover - Germany

INTRODUCTION - The regulation (EU) 6/2019 foresees that in a few years special GMP-guidelines for autogenous vaccines shall be approved to facilitate free trade. The focus in this contribution is on personnel and premises in the production.

CHALLENGES - Because there is no registration and approval process for these products quality and safety are only guaranteed by the circumstances of every local production. The prevention of contaminations from environment and operators is most important. Further aspects are the very variable production processes because of very different batch sizes and antigens. Premises for multiple purposes are needed. A lot of working operations have to be done manually with open product. Nevertheless the production has to be carried out under aseptical conditions. So the current GMP-guidelines are not completely applicable.

Competence, integrity and experience of the qualified person who releases the products is even more important than for licensed vaccines because the qualified person is the only batch-related authority to assure safety and quality. PROPOSED APPROACH - The current EU-GMP-guidelines can give orientation. But the new GMP-guidelines should differ from them to meet the special requirements for the autogenous vaccines based on a risk management process - taking also in consideration the limited use in a low number of animal holdings.

Abstract

Iska Lehmann

2/2

Generally, requirements for operators should be similar to current EU-GMP, for functional personnel even higher. For the production of vaccines for parenteral use there should be clean rooms comparable to clean rooms of the current EU-GMP-guidelines classes C and D. Open working steps should be done in class A work benches or similar. Important aspects like, for example, classification and monitoring should be regulated, too, but appropriately.

CONCLUSIONS – Basically, it has to be a political decision that the level of the future GMP-requirements for the production of autogenous vaccines is defined below the level of current EU-GMP to keep production in Europe ongoing. Therefore, separate GMP-guidelines should be implemented.

Jordi Lopez

Aquaculture and the use of autogenous vaccines for fishes

Coordinator / Professor - FEADSA / Universidad CEU Cardenal Herrera
Feadsa - Spain

Although we talk about aquaculture, there are many different aquacultures. EU sector is producing 35 different species (Atlantic Salmon, Rainbow Trout, Carp, European Seabass, Eel, Meagre…), and are produced in different environments (fresh water, sea farms, brackish water), in several producing systems (sea cages, recirculating, open systems…). This implies great differences on the pathogens affecting farms, making complicated the registration of vaccines for aquaculture due to small market for those products.

That's the reason for having such few vaccines registered for minor species (those different to Atlantic Salmon). In addition, some of these vaccines are old registers, from 90's, so are not fully efficient, due to the appearance of new strains. Only Salmon sector has many different registered vaccines available for a wide number of pathogens.

The use of autogenous vaccines is not homogeneous around EU. Some countries allow it's use as an effective way to control some diseases without registered vaccines, while in other countries the producers are not using autogenous vaccines at all, due to different reasons: national restrictions, sector size…

The new Regulation 2019/6 entering into force next year is supposed to solve this problem, helping to standardize the procedures to prescribe, manufacture and use of autogenous vaccines.

In conclusion, even though there are many difficulties to get both registered and autogenous vaccines, the new VM Regulation is a hope to have a greater availability of immunological products in aquaculture, helping to reduce the impact of diseases and the use of antibiotics in fish production.

Dries Minne

Current situation on the Autogenous Vaccines in Belgium: Challenges and the way forwards

Head of the Veterinary Division - FAMHP
Brussels - Belgium

Introduction: Currently there is no specific legislation on the autogenous vaccines in Belgium. The article 3 of the directive 2001/82 as amended by directive 2004/82 was transposed in the national Medicines Legislation. But there are no specific rules to regulate the production, import, export use and surveillance of autogenous products in Belgium.

Challenges: The absence of a clear legal framework leads to an ambiguous situation where different players use different standards, an absence of a level playing field, ignorance on what happens on the market and legal provisions that are no longer in line with the current integrated breeding/ rearing/production.

Proposed solutions: The regulation 2019/6/EC already solves some of the loopholes within the current legislative framework. One of these solutions is that the scope of autogenous vaccines is extended to the use in epidemiological linked units or localities. Also the absence of harmonized quality standards for the production of autogenous vaccines will be tackled by means of the implementing act on GMP requirements that will be drafted by January 2025. However, there are further possibilities on national/EU level to improve the legal framework for autogenous vaccines.

Conclusion: The Regulation 2019/6/EC will introduce some significant improvements at the level of the regulatory framework for autogenous vaccines, but by means of subsidiary national/EU guidance there is room for further improvement.

Petra Műllerová

Requirements for the manufacture, control, prescription and use of veterinary medicinal products autogenous vaccines in the Czech Republic

Director of Inspection Department - ÚSKVBL
Brno - Czech Republic

Institute for State Control of Veterinary Biologicals and Medicines (USKVBL), Brno, Czech Republic

Keywords: veterinary autogenous vaccines, use, prescription, USKVBL, Czech Republic

INTRODUCTION – Requirements for veterinary autogenous vaccines are based in national legislation in the Act No. 378/2007, on Pharmaceuticals and its implementing regulation. Absence of rules for VAVs in the EU level lead to preparation of national guideline for detailed regulation of production, inspection, prescription and use of veterinary autogenous vaccines which was issued in 2003. Thanks to the collection of data on production of veterinary autogenous vaccines we can present the amount of production, used antigens and animal species from 2006 – 2020.

ISSUES – Requirements for the manufacture, control, prescription and use of veterinary medicinal products autogenous vaccines in the Czech Republic have been set in such a way that since 2003 they correspond to the requirements set by the Regulation (EU) 2019/6 on veterinary medicinal products and repealing Directive 2001/82/EC.
The production and use of a veterinary autogenous vaccine should always be an emergency solution to the health situation in a particular herd in a given locality provided, however, that there is no authorised veterinary immunological medicinal product to solve this situation or if it has been demonstrated that the use of an authorised veterinary medicinal product in the breed did not solve the current disease situation.
Production of a veterinary autogenous vaccine can be initiated only on the basis of the "Prescription for the Production of a Veterinary Autogenous Vaccine" issued by an attending veterinarian. Veterinary autogenous vaccines

Abstract

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are manufactured exclusively from the pathogens or antigens, which were obtained in a particular herd in a given locality, and may be used only in this herd in the given locality. Always before commencing the production of each batch of a veterinary autogenous vaccine, the manufacturer sends "Notice of the Commencement of Production of a Veterinary Autogenous Vaccine" to ÚSKVBL and the Regional Veterinary Administration, in which area of competence the veterinary autogenous vaccine will be used.
All manufacturers in Czech Republic must obtain Manufacturing Authorization from ÚSKVBL and are inspected in regular intervals at least once in 2 year. During the production, the manufacturer is obliged to comply with the requirements of good manufacturing practice for the given pharmaceutical form and produced the veterinary autogenous vaccine in accordance with the applicable Manufacturing Authorisation.
The highest production of VAVs in CZ was recorded in 2006-2008 when it reached the number of 846 batches produced. Since 2013, between 300 – 400 batches of VAV have been produced per year. There are three Czech manufacturers (311 batches produced per year 2020), two German manufacturers (46 batches produced per year 2020) and 1 Slovac manufacturer (1 batch produced per year 2020) whose VAVs are used in CZ market. VAVs against respiratory (40%) and enteral infections (27%) in cattle and pigs (respiratory – 46%, enteral – 25%) greatly prevail.

PROPOSED APPROACH – Harmonization of requirements for VAVs across the EU with a view to their use as one of the instruments used in reducing of use of antibacterial substances. Preparation on new guidance on GMP for veterinary autogenous vaccines in the cooperation between EMA and PIC/S.

CONCLUSIONS – In Czech Republic the veterinary autogenous vaccines are well – established and regulated in compliance with the requirement of the Regulation (EU) 2019/6 on veterinary medicinal products and repealing Directive 2001/82/EC. The detailed requirements are set out in the national Guidance ÚSKVBL/INS-02/2021. Whereas in the Czech Republic veterinary autogenous vaccines are produced both for their own market and for export purposes and are also produced in other EU countries for use in the Czech Republic, the ongoing effort to harmonize the production and use of veterinary autogenous vaccines is supported by ÚSKVBL.

Brigitte Othmar-Vielitz

Starting materials and seeds

EMAV
Cuxhaven - Germany

The EMAV-Proposal for the new EU-GMP-Annex for Autogenous vaccines also includes requirements for the quality of starting materials including viral seeds.

Starting materials in the manufacture of autogenous vaccines can be of various kind and origin. The introduction of new harmonized rules governing starting materials of autogenous vaccines will be an additional regulatory burden for the manufacturers. Since the risk of the use of inactivated autogenous vaccines is low due to local application within epidemiological units only and the benefit of filling a therapeutic gap his high, it is necessary to reduce the regulatory burden for such starting materials to a reasonable degree.

It is generally accepted that viral seeds as starting materials can potentially be contaminated with extraneous viruses which requires additional and careful attention. Maybe this is the reason why currently a number of European countries do not accept viruses as potential starting materials for autogenous vaccines. This is mainly manifested in national regulations that exclude the use of viruses in the manufacture of autogenous vaccines. However veterinarians urgently need viral autogenous vaccines to fill therapeutic gaps.

For the control of starting materials EMAV proposes that supplier qualification should be limited to excipients, adjuvants and primary packaging materials and should be paper based only. Incoming goods control is limited to correspondence of the supplier's certificate and the specification. Storage of reference samples of starting materials is reduced and limited. Purified virus must be free of extraneous agents based on risk analysis and testing, i.e. extraneous agents testing is limited to those agents not excluded by risk analysis. There is no requirement for animal trials, but test validation and LOD are sufficient. Starting materials can be used under quarantine before they are released.

Conclusions: The EMAV proposal for starting materials including viral seeds sufficiently controls their quality and at the same time does not compromise significantly the speed of supply of autogenous vaccines and their justification of use, which is "the filling of therapeutic gaps as requested by veterinarians and the current animal health status.

Dietrich Rassow

Expectations from different stakeholders – german national authority

CVO - Federal Ministry of Food and Agriculture
Germany

Autogenous vaccines are subject to complex European legislation comprising both regulations for immunological veterinary medical products and animal health. In order for Member States to prepare for the implementation of new rules on autogenous vaccines it is important to consider the interaction between different regulations and to take into account important definitions such as for epidemiological unit / epidemiological link. Respective legislative procedures at European and national level are currently ongoing and far from over. The presentation covers a brief legal overview and the viewpoint of the competent National authority of Germany.

Mariette Salery

Autogenous Vaccines and regulation 2019/6

Expert in Immunological Products - ANSES-ANMV
Fougères - France

Autogenous vaccines : from a legislation to another one :

Background :

While inactivated autogenous vaccines were out of the scope of the 2001/82 directive, they will be regulated, partially, by the regulation EU 2019/6. There is currently no other EU harmonisation of requirements regulating autogenous vaccines than the one prepared by the CMDv in 2016. The change of regulation is an opportunity to go ahead on the harmonisation.
Proposed Approach and Relevant Guidance:
The speech will present the current and the future situation from a regulatory point of view. Currently the autogenous vaccines are defined in the 2001/82 directive but excluded from its scope. In parallel, in EU, there are different national regulation and a CMDv recommendation paper.
In the future, inactivated autogenous vaccine will be in the scope of the EU 2019/6 regulation and covered by a limited number of articles. The main change is that Good Manufacturing Practices guidance is foreseen to cover the manufacture requirements and will be developed and applicable in January 2025.

However not all the aspects of the autogenous vaccines will be covered by either the regulation or the GMP guidance. Therefore a kind of EU guidance will still be needed for those topics of interest for national authorities so that they will be able to regulate the authorisation, the use, the control, the surveillance and the movement of these medicines.

Conclusions:
Change of regulation is challenging for every parties. On one side, identification of issues triggered by this change may be dizzying, on the other side, it is an opportunity to improve the public and animal health condition, offering high quality autogenous vaccines to be used on the field.

Ynte Schukken

Autogenous Vaccine Production: Challenges and Opportunities

CEO - Royal GD
Deventer - the Netherlands

BACKGROUND : Autogenous vaccines have been used for a very long time. The production of autogenous vaccines is now receiving the necessary attention in European regulations. It is important to understand the market forces and the scientific forces underlying the use of autogenous vaccines. Both market forces and scientific forces pose challenges and opportunities.

CHALLENGES : Vaccination of animals has been shown to be an effective tool in prevention or reduction of the impact of infectious diseases in individual animals and populations of animals. Commercial vaccines need to show in the process of licensing that the product is safe and efficacious. Currently the safety and efficacy of autogenous vaccines is at best unknown and given the population [farm]-specific nature of these vaccines and the large variation in vaccine production practices it is a challenge to convince users and regulators that there is a long-term need for such vaccines.

OPPORTUNITIES : The first and probably most important opportunity lies in Improving and securing the production processes of autogenous vaccines so that the precautionary principles ['do not harm'] are met when veterinarians make use autogenous vaccines. Working together as autogenous vaccine producers provides an opportunity for safeguarding animal health. When the ultimate goal of our profession is to improve animal health, it is also essential that autogenous vaccine producers are in close communication with producers of licensed vaccines.

Abstract

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Ultimately, securing both safety and efficacy of vaccines is the penultimate goal of animal health professionals. The well thought out phases of securing efficacy of vaccines are essentially out of reach for autogenous vaccines. Still, the potential value of reducing the impact of an homologous challenge is evident from both a theoretical and practical point of view. The temporary, until a licensed vaccine is available, or more permanent, for application where no licensed vaccine is or will be available, application of autogenous vaccines provides an opportunity in improving animal health.

CONCLUSIONS : The production and use of autogenous vaccines provide challenges and opportunities in the field of animal health. By safeguarding production practices an important and relevant concern has been addressed. Further opportunities for rational use remain.

Annie Sigognault-Flochlay

Manufacturing and control of viral vaccines: Specific challenges for autogenous products

Director R&D, Qualified Person, Deputy General Manager
FILAVIE
Sèvremoine - France

The success of an autogenous viral vaccine not only relies on the right selection of the virus strain responsible for an emerging or severe epidemiological situation, but also to the ability of the manufacturer to operate within a compressed development and production lead-time to address urgent needs while delivering a robust, pure and safe product.

The specificity of viral autogenous vaccines for vaccine manufacturers also lies in the diversity of virus species and/or strains processed in parallel, and in the very small production batch sizes inherent to custom-made products.

The high degree of variability of production conditions and the multiplicity of control methods validation steps, particularly antigen inactivation, multiplies manufacturing, testing and quality monitoring acts. The presentation discusses how autogenous vaccine manufacturers' commitment related to quality, robustness and safety can remain implemented under those specific conditions, through targeted adaptations of quality control, manufacturing and testing good practices.

Ewald Van Kuppeveld

Autogenous Vaccines: Monitoring of premises and Personnel from perspective of the Industry

Ripac - Germany

This presentation is about the required general aspects of premises suitable for the manufacture of autogenous vaccines from the perspective of the Industry. To ensure the quality of the autogenous vaccines the manufacturing should be done in premises with appropriate cleanrooms. Within these cleanrooms a variety of manufacturing activities will be executed. So manufacturing activities need different cleanroom classification to ensure the required quality.
The cleanroom classification / grades must be accompanied with a suitable environmental monitoring program. A robust monitoring program should be established based on a risk assessment and consists of an array of parameters. The cleanroom grades and its monitoring program will be discussed.
Besides premises, personnel is needed to manufacture autogenous vaccines with its requested quality. To ensure this, personnel should be trained for several items like hygiene, assigned duties, testing and processes

Grégory Verdier

Feedback and contribution from French inspectorate perspective

Head of Inspection Unit - : French Agency for Veterinary Medicinal Products (Anses-ANMV)
Fougères - France

Introduction: Autogenous vaccines are major and useful tool to reduce the use of antimicrobials in animals, to control emerging infectious diseases, and to contribute to animal well-being and welfare. Even if there are employed in exceptional circumstances, they are widely used in France, across EEA and beyond.

Challenges: Autogenous vaccines are veterinary medicinal products with numerous specificities: they are complex biological products, produced in a non-industrial way. They include a wide variety of antigens and a certain degree of variability. They are usually made fairly quickly (4-8 weeks) and in small batches. The evolving regulatory context at EU level provides an opportunity to take a look at what has been done and what could be done regarding autogenous vaccines, their characteristics and their manufacture.
Proposed Approach: Autogenous vaccines have been regulated in France from more than 20 years. On the strength of this experience, the French inspectorate gives a feedback of the management of autogenous vaccines manufacturing at national level. This analysis is the starting point for recommendations for the future GMP for autogenous vaccines considered following the adoption of the EU regulation 2019/06.

Conclusions: the implementation of GMP for autogenous vaccines at European level will be an opportunity for a harmonisation across Europe. In a globalized word, with the increase in infectious diseases associated this increased travel and trade, this harmonisation approach would need to go further. Pharmaceutical Inspection Co-operation Scheme (PIC/S) or OIE could be potential place and resource for establishing and promoting international guideline or regulation that facilitate the production and use of autogenous vaccine.

Florian Voisin

Autogenous Vaccines: an insight of their use by French pig practitioners

DVM, CEAV, DIU Cesam - Hyovet
Plestan - France

Over the last ten year the French pig industry has dramatically dropped the use of antibiotics. Prevention through technical measures, hygiene, and vaccination has become the major recommendations of the French vets.

Facing the changes of mentality, the main prescription of the French vets in the pig industry have changed from antibiotics to vaccination programs. Between 2008 and 2017 the antibiotics included in the production costs of 100kg carcass have dropped from 2€60 to 1€25. In the same time, the investment in vaccines has grown from 2€50 to 3€50 for 100kg carcass. The French pig industry sells now worldwide pork from pigs raised without antibiotics. This has been possible only by focusing on the basics of zootechny, nutrition, biosecurity and targeting the pathogens through hygiene and vaccination strategies among which autogenous vaccines have their role to play.

Max Bastian

Secretary of the Standing Committee
on Veterinary Vaccines
Friedrich-Loeffler-Institute - Suedufer 10
D-17493
Greifswald – Insel Riems
Tel: +49 38351 71026
e-mail: max.bastian@fli.de

Education

10/1993 – 07/1999	Studies of Veterinary Medicine, University of Veterinary Medicine, Hannover
01/2000 – 02/2004	PhD thesis (Doktorarbeit), Swiss Tropical Institute, Basel, and University of Veterinary Medicine, Hannover
03/2015	Veterinary specialist for microbiology (Fachtierarzt)

Professionnal experience:

03/2004 – 12/2008	Postdoctoral Fellow, Institute for Clinical Microbiology, Immunolgy and Hygiene, Erlangen University and Institute for Medical Microbiology, Ulm University
01/2009 – 09/2015	Group Leader, Department of Veterinary Medicine, Paul-Ehrlich-Institute, Langen
Since 09/2015	Secretary of the Standing Committee on Veterinary Vaccines at the Friedrich-Loeffler-Institute

Klaus-Peter Behr

Managing Director - AniCon Labor GmbH
Muehlenstrasse 13 - 49685
Hoeltinghausen - Germany
Tel: + 49 171 4169 110
e-mail: behr@anicon.eu

Klaus-Peter Behr studied veterinary medicine in Hannover, Germany, until 1984, obtained his doctorate there in 1986 and served as a research assistant at the University of Veterinary Medicine in Hannover until 1992.

From 1992 until 2005 he worked as senior veterinarian and head of laboratory services in an integrated company in the german poultry industry.
For the past 16 years, Klaus-Peter Behr has headed AniCon Labor GmbH, which he founded in 2005, and he also runs companies active in animal disease control.

Klaus-Peter Behr is a specialist veterinarian for poultry and a Diplomate of the European College of Poultry veterinary Science (ECPVS). Klaus-Peter Behr also took the initiative to found EMAV and has served as its chairman since 2019.

Biosketch

Wiebke Bielenberg

Wiebke Bielenberg

Head of Production, Qualified Person - AniCon Labor GmbH
Mühlenstr. 13 - 49685
Höltinghausen - Germany
Tel: +49 4473 9438 27
e-mail: bielenberg@anicon.eu

Wiebke studied biochemistry and received her diploma in 2006 at Leibniz University Hannover.

After one year as post-doc in human medicine she started working at AniCon in the production and control of autogenous vaccines with special focus on viral vaccines.

Wiebke is member of EMAV and part of the Scientific working group within EMAV.

Rosario Bullido

Head of Veterinary Biologicals - Immunologiscals Assessment Unit. Veterinary Medicines Department - Spanish Medicines and Medical Devices Agency
Calle Campezo 1 - Edificio 8 - E-28022 Madrid Spain
Tel: (+34) 918225419
e-mail: rbullido@aemps.es

Head of BIO-IMMUNO veterinay assesment unit in AEMPS (Spanish Medicines and medical devices Agency). I have been working in the Spanish Medicine Agency since 2001 (Veterinary Department). As part of this work I am member of IWP-Immunological Working Party (EMA) and 15V group veterinary vaccines (EDQM).
I have also participate in other groups and in the development and/or revisión of veterinary medicines legislation and guidelines, as in expert group as in Autogenous vaccines (CMDv), Regulation 6/2019 (Annex II), ATA (Alternatives to antimicrobials), Monoclonal antibodies (ADVENT, Novel therapy), etc.

PhD in veterinary immunology (Complutense University of Madrid- CISA-INIA Valdeolmos. Madrid) in porcine immunology. Post-doc fellowship in fish immunology (CISA-INIA) and in human influenza virus molecular biology - Instituto Carlos III. Madrid.

Santiago Cabaleiro

Director - Centro Tecnológico del Cluster de la Acuicultura (CETGA)
Punt de Couso -Ribeira (A Coruña) - 15965, Spain
Tel: +98841600
e-mail: cabaleiro@cetga.org

Dr. Cabaleiro is PhD, MSc In Chemistry and is the Director of the Centre Technological of Cluster of the Aquaculture that belong to the main aquaculture companies and is the main private research center for aquaculture in Spain). He has more than 20 years' experience in this aquaculture field and currently he manager and scientific coordination of the center.

Dr. Cabaleiro has focus his research in develop new vaccines for aquaculture fish in special vaccine against protozoan and myxozoan. Recently he has developed several research projects in genetics in the relation with the QTLS and SNIPs with Infectivity, tolerance, and resilience in fish.
He was Vice-chairman in the FEAP (Federation of European Aquaculture Producers) for three years; also, he was the Aquaculture chairman of CYTED an international research program between Latin-American and Portugal and Spain and he was Assistant professor in the University of Vigo and Technical Director of and Analytical lab for research in Environmental and Food processing.

Since 2017 he is Board Director of the EATIP (European Aquaculture Technology and Innovation Platform))", and in 2017 it was participated as scientific member in High Level Group of Scientific Advisors European commission Directorate-General for Research and Innovation in the proposal Food form the Oceans.
In his assignment as FAO senior expert in "Fish Aquaculture vaccines used in KSA and commercial fish farming" of the thematic cluster "Sustainable marine fisheries and aquaculture production and consumption".
He has published over 40 peer reviewed scientific papers and over 60 research projects Framework, VI, VII and H2020 as international and private research projects.

Panos Christofilogiannis

Director - Aquatreck Animal Health
A Relva s/n. Torneiros - 36410 O Porriño
Pontevedra - Spain
Tel: +306944418566
e-mail: panos@aquatreck.com
URL: www.aquatreck.com

Dr. Panos Christofilogiannis (DVM, MSc, and MSc, PhD) is fish health expert with deep knowledge and 27 years of experience on applied research and technology transfer in European aquaculture industry with special focus on technology transfer and testing of innovative fish health management strategies and novel vaccine development. Panos is Managing Director AQUARK (www.aquark.eu) since 2004 and Founding partner and Director of AQUATRECK ANIMAL HEALTH S.L (www,aquatreck.com) since 2019. AQUATRECK ANIMAL HEALTH S.L is a new generation AQUA pharmaceutical company incorporated in OPorriño, Pontevedra Spain when CZ VACCINES S.A established in Spain and MARINNOVAC Limited established in Ireland joined forces to re-invent fish health management and support the aquaculture industry's sustainable growth. AQUATRECK is thriving in developing classic and novel technology (subunit) viral, bacterial and parasitic autogenous, experimental and licensed vaccines.

The AQUATRECK mission is to fast-track innovative fish & shrimp disease prevention strategies by building effective open collaboration alliances of top talented teams to serve the global aquaculture industry's sustainable future. AQUATRECK has a GMP Vaccine production facility in Galicia, Spain, a VMD approved AV production lab in Marinnovac UK Ltd in Cambridge, UK, a Biotechnology R&D center specialized in Pichia pastoris novel subunit vaccine technologies in Dortmund, GE and a Bacteriology R&D lab in Santiago de Compostela, ES. We thrive in open innovation and collaboration with a wide network of fish health experts through various research funded projects like www.targetfish.eu , www.parafishcontrol.eu , www.performfish.eu , www.medaid-h2020.eu/ and others.

Rory Conney

Head of Biologicals - Veterinary Medicines Directorate (VMD)
Woodham Lane, New Haw
Addlestone, Surrey KT15 3LS - United Kingdom
Tel: +44 1932 336911
e-mail: r.cooney@vmd.gov.uk

Head of Biologicals Section at the Veterinary Medicines Directorate (VMD), UK. My role is to lead the team responsible for the quality, safety, efficacy and benefit:risk balance of biological veterinary medicines on the UK market.

Sebastien Deville

Europe Business Development & Open Innovation Manager Vaccine Adjuvant Market - SEPPIC
SEPPIC | Air Liquide Healthcare Specialty Ingredients - Paris La Défense - 50 boulevard National - CS 90020 - 92257 La Garenne Colombes Cedex - France

Sebastien Deville is a biology engineer and graduated from CNAM Paris. He joined Seppic in 1996.

Over the last 25 years, S.Deville worked for Adjuvant and Injectable business unit but also to the Pharma excipient division in SEPPIC. He started his Seppic career working in our immunology laboratory as a technician. After 10 years, he moved to the management of the Scientific marketing in our HQ team based in Paris. He then moved to Mumbai, India, in 2011 to support business development of the Adjuvant, Vaccine & Injectable (A.V.I.) unit. After another position in Paris as Business Development Manager for the Pharmacy BU, he moved again to Asia, this time for the SEPPIC office in Shanghai, China, to be in charge of the A.V.I markets. After July 2020 S.Deville returned to a position in sales in Europe and is now managing the A.V.I. business in this area as well as the Excipient open innovation program for SEPPIC.

Nancy De Briyne

Executive Director of the Federation of Veterinarians of Europe (FVE)
Ghent - Belgium

Nancy De Briyne studied veterinary medicine in Ghent (Belgium), graduating in 1996. After working as a veterinary practitioner in Belgium and the UK, she works since 2000 for the Federation of Veterinarians of Europe (FVE).

Within FVE she is specifically responsible for dossiers in field of veterinary medicines, animal welfare, education and communication. Presently, she is Deputy Executive Director of the FVE. In respect to medicines, she published papers on factors influencing prescription behaviour, antibiotic sensitivity testing, antibiotics most commonly prescribed for animals, alternatives to antibiotic treatments and adverse events of medicines.

She is member of the Management Board of the European Medicines Agency representing the veterinary profession. In respect to animal welfare, in 2015, she became diplomate of the European College of Animal Welfare and Behavioural medicine, subspecialty Animal Welfare Science, Ethics and Law. She has worked extensively in the field of transport of animals (being core partner in the EU Animal Transport Guides Project), pig welfare (pig castration, tail docking), cattle welfare, companion animal welfare and animal welfare science, ethics and law teaching in veterinary education. She is member of the EU Platform on Animal Welfare and EFSA hearing export on the transport of animals.

Jean De Foucauld

Senior Biology Expert - Ceva Santé Animale
10, Avenue de la Ballastière
33500 Libourne - France
Tel: +33 7 60 47 90 45
e-mail: jean.de-foucauld@ceva.com

Jean de Foucauld graduated as a doctor of veterinary medicine in France and since then, has been working in the field of vaccine manufacturing, development and regulatory affairs. He has a practical experience on veterinary vaccine development from positions he held in many parts of the world, particularly in Europe, the USA, Japan and China.

Since twenty years, he works for Ceva Santé Animale.
First working at Ceva main Bio centre for Ceva in Budapest, he was the head of vaccine regulatory affairs and clinical development for the company. Based now in France, he leads specific projects, with a focus on 'novel technology' vaccines. He is also involved in the development and regulatory aspects of Ceva autogenous vaccines in Europe and abroad. He sits at EMAV's Scientific Working Group.

Maarten De Gussem

Managing Director - Poulpharm
Prins Albertlaan 112
8870 Izegem - Belgium
Tel: ++32 473 999 379
e-mail: maarten.degussem@vetworks.eu

Maarten De Gussem graduated as a DVM from Faculty of Veterinary Medicine at Ghent University in 2000 with a thesis on Infectious Bursal Disease Virus at the University of Arkansas, USA.

He began working in the field at DEGUDAP group practice in France, The Netherlands and Belgium, dealing with layers, breeders, broilers and turkeys. In 2001, Maarten joined the division of J&J Global Poultry Technical Manager at Janssen Animal Health, with focus on coccidiosis, gut health, helminthosis, histomonosis and red mite.

In 2009, Vetworks was founded by Maarten, servicing the poultry industry with a global team of specialists and providing support on poultry health topics all over the world, with focus on mycoplasmosis, general gut health and coccidiosis.

Besides his work at Vetworks, Maarten is also an academic adviser at the Faculty of Veterinary Medicine at Ghent University. And a member of scientific committees of Poultry Mycoplasma Conference and of IHSIG Conference on Poultry Intestinal Health.

Maarten De Gussem is also author of Broiler Signals, a leading broiler management book in more than 12 languages.

Laurent Drouet

PHARM D
QP Ceva Biovac - Ceva Biovac
6 rue Olivier de Serres
49070 Beaucouzé - France
Tel: +33 762676718
e-mail: laurent.drouet@ceva.com

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Erno Horvath

Head of Inspectorate - National Food Chain Safety Office
Directorate for Veterinary Medicinal Products
Budapest - Hungary

Veterinarian (graduate) and agricultural biotechnological research engineer (postgradute).

Positions:

*2013- Head of Inspectorate
National Food Chain Safety Office
Directorate for Veterinary Medicinal Products
*2007 – 2013 Assesor for poultry vaccines
*2005- 2007 Head of Poultry Department
2004-2005 Scientific administrator (EMA)
*1990-2004 Head of Poultry Department
*1987- 1990 Laboratory veterinarian
*The workplace was the same with different names
1980-1987 Veterinary at the Frontier Guard
I have expertise in assessing marketing authorisation dossiers and laboratory activities, leading inspection of veterinary medicinal manufacturers including vaccines and pharmaceuticals.

Memberships
Member of European Pharmacopoeia Group 15V since 2001
Hungarian Society of Zoonoses since 1992
Hungarian Society for Microbiology since 1989
Hungarian Veterinary Poultry Association since 1989

Biosketch

Erno Horvath

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Most important fellowships
1, Cohran fellowship training (USA)
1993, 3 weeks (inspection, monitoring system, vaccine control)
3, VLA training (United Kingdom)
1998, 2 weeks (new methods in the lab)
Publications

11 th Hungarian Congress of Microbiology 91
Mészáros, J., Horváth, E., Polyák-Nagy,E.,
Oral immunization against Newcastle Disease with the vaccines Vitapest and Phylavac

Acta Veterinaria Hungarica 40 (4), pp.323-328 (1992)
L.Tekes , E. Horváth, Edith Nagy
Checking of immunity against Newcastle Disease by ELISA

Magyar Állatorvosok Lapja 1994/3
Glávits Róbert, Ivanics Éva, Rátz Ferenc, Tekes Lajos, Horváth Ernő, Nagy Edith, Révész Tamás
Patomorfológiai megfigyelések velogén baromfipestis-vírussal kísérletesen fertőzött, különböző immunitású broilercsirkékben

Acta Veterinaria Hungarica 47 (4), pp. 481-492 (1999)
I.Fodor, E. Horváth, Nadja Fodor, Edith Nagy, Altancsimeg Rencendorsh, V.N. Vakharia, S.K. Dube
Induction of protective immunity in chicken immunised with plasmid DNA encoding Infectious Bursal Disease

Vaccine 17 (1999) 2969-2973
E. Horváth, G. Czifra, E. Nagy, B. Enström, M, Mérza
Potency test of inactivated Newcastle Disease vaccines by monoclonal antibody blocking ELISA

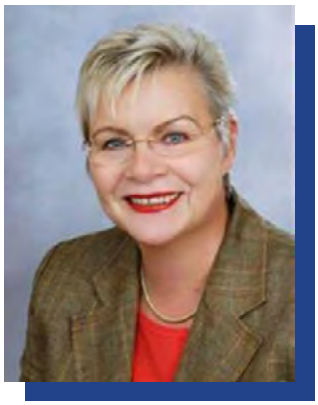
David John

Senior Technical Manager - AnimalhealthEurope
168 Avenue de Tervueren Box 8
Brussels 1150 - Belgium
Tel: +32 2 543 75 78
e-mail: d.john@animalhealtheurope.eu

Education: David graduated in Agricultural Chemistry from Leeds University in 1988

Career to date: David joined the technical group at AnimalhealthEurope (IFAH-Europe at that time) in 2011 and is currently a Technical Manager responsible for Biologicals.

Prior to joining AnimalhealthEurope he spent many years working for Covance initially responsible for conducting livestock metabolism and residue studies before moving to ecotoxicology to conduct both aquatic and terrestrial studies.



Carmen Jungbäeck

Board Member
Vice-Chair, IABS-EU
USA

Dr Carmen Jungbäck graduated from the Tierärztliche Hochschule, Hannover with a degree in Veterinary Medicine. In 1981, after a few years as an animal surgeon she joined the Paul-Ehrlich-Institut, (Federal Agency for Sera and Vaccines), Langen, Germany, where she was Head of the section Veterinary Virology 1 until retirement in 2016. The section's area of activities comprises vaccine licensing and testing, with special expertise in viral vaccines for poultry. In this context, the practical testing of vaccines during licensing and for official batch release is one of the major responsibilities.

She was also member of a number of advisory boards to the EDQM-OMCL Network, Ph.Eur Group 15V and CVMP-IWP and JEG3R at EMA dealing with IVMPs under various aspects.

At IABS she is member of the board and Chair of the Veterinary Biologicals Committee and Vice-President of IABS - EU. She is organizing IABS meetings focusing on the veterinary field. As member of IABS-EU she is involved in the IMIprojects (ZAPI and Vac2Vac).

Dietmar Katinger

CEO - Polymun Scientific Immunbiologische Forschung GmbH
Donaustr. 99, 3400 Klosterneuburg, Austria
Tel: + 43 2243 25060 300
Fax: + 43 2243 25060 399
e-mail: dietmar.katinger@polymun.com

Since December 2010, Dietmar Katinger is CEO of Polymun Scientific GmbH, a private GMP-compliant company offering contract development and manufacturing of biopharmaceuticals as well as liposomal formulations, where he was already responsible for business development since 2003.

Before, he worked in the virology team of Polymun on the development of a live attenuated influenza vaccine. Dietmar Katinger received his Ph.D. degree in 1999 at the University of Natural Resources and Applied Life Sciences, Vienna, with the thesis "Steps towards a Live Attenuated and Cold-adapted Influenza Vaccine Produced on the Vero Cell Line", supervised by Dr. Noel Barrett and Prof. Friedrich Dorner, both Baxter Healthcare (now Takeda). He received his Master degree with a thesis about the characterization of a human monoclonal antibody against HIV-1 in 1994, partly carried out at the University of Bath, UK. Dr. Dietmar Katinger has graduated as an Executive MBA at the IMADEC University, Vienna, in 2006.

Dietmar Katinger is co-founder of BS-Immun GmbH, an Austrian manufacturer of autogenous vaccines for veterinary use since 2010, and member of the scientific working group of EMAV.

Vaughn Kubiak

Retired/Consultant - Independent
2 Lieu-dit Matorges
42130 Trelins - France
Tel: +33 6 64 00 07 66
e-mail: vaughn.kubiak@outlook.com

Vaughn Kubiak has over 40 years of experience in global animal health, with a primary focus on development, licensure, and maintenance of global veterinary biologicals. He has helped develop and improve conventional and innovative immunological veterinary medicinal products for all major species during his career.

Vaughn has worked for a number of global animal health companies, with positions in R&D, QA/QC, regulatory affairs, product management, and commercial operations. Prior to his retirement from full-time activities in 2019, Vaughn spent the last 17 years with Zoetis Inc., where he held management positions in Regulatory Affairs, Biologicals Process Development, and Biological Analytical Development. During his last role in Zoetis (2009 – 2019), he was responsible for the European, Middle East, and African Biological Regulatory Affairs team in Sandwich, England and then Zaventem, Belgium.

Vaughn remains connected to the Animal Health Industry, however, through limited consulting. He holds Bachelor of Science and Master of Science degrees in Microbiology from the Ohio State University and Emory University, respectively.

Jordi Lopez

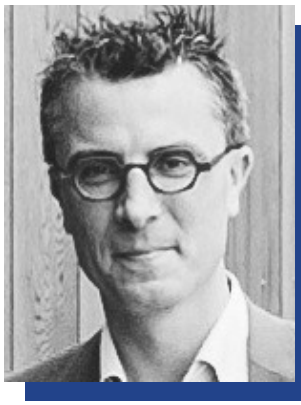
Coordinator / Professor - FEADSA / Universidad CEU Cardenal Herrera
C/ Tirant lo Blanc, 7
46115 Alfara del Patriarca Valencia - Spain
Tel: +34606266916
e-mail: j.lopez@feadsa.es / jordi.lopez1@uchceu.es

Degree in Veterinary Medicine from University CEU Cardenal Herrera. Doctor from the Polytechnic University of Valencia.

Since 2005 he has worked as veterinarian specialized in aquaculture production and health management, being Veterinary Technical Manager of the different Health Defense Groups in Valencia and Canary Islands. Since 2010 he is the Coordinator of the Technical Committee of the Spanish Federation of Aquaculture Health Defense Groups (FEADSA). He is part of various committees and working groups, both nationally (Vet + i, AEMPS, INIA ...), and internationally (FEAP, FVE, FishMedPlus ...).

Since 2013 he has been a professor at the University CEU Cardenal Herrera's Faculty of Veterinary Medicine, teaching both the Bachelor's Degree in Veterinary Medicine and the Master's Degree in Food Safety.

He has several published books in the field of aquaculture and animal production.



Dries Minne

Head of the Veterinary Division - FAMHP
Galileelaan 5/03 - 1210 Brussels - Belgium
Tel: +32 (0) 2 528 41 27
Fax: +32 (0) 2 528 41 36
e-mail: dries.minne@fagg-afmps.be

Dries qualified as a pharmacist and holds an additional degree of Master in Business Planning. He started working in regulatory affairs for human medicinal products in 2003 in the pharmaceutical company Pfizer. In 2004 he made the shift to the Belgian Federal Agency on Medicines where he started working as project manager for veterinary medicinal products.

Since 2010 Dries is the Head of the veterinary division within the Federal Agency on Medicines and Health Products. As delegate in the council working party on veterinary medicines he was also involved in the elaboration of the Regulation 2019/6/EC on veterinary medicines.

Dries is also the Belgian delegate in multiple EU committees and working groups such as the Standing committee, pharmaceutical committee, CMDv, QRD and NtA. Since 2019 Dries is also the chair of the CMDv Legislation working group. This working group is responsible to coordinate the implementation of the Regulation at the level of the CMDv.

Petra Műllerová

Director of Inspection Department - ÚSKVBL
Hudcova 56a,
621 00 Brno, Czech Republic
Tel: + 420 541 518 276
Fax: + 420 541 212 607
e-mail: mullerova@uskvbl.cz

Petra Műllerová graduated from Brno University of Veterinary and Pharmaceutical Sciences, Faculty of Veterinary Hygiene and Ecology, in 2000 with Doctor of Veterinary Medicine title. In the years 2000-2002 she worked in the position of GDP inspector at the Institute for State Control of Veterinary Biologicals and Medicines (USKVBL), Brno, Czech Republic. In 2002 she obtained Attestation of the 1st grade, in 2010 she obtained Attestation of the 2nd grade - specialization laboratory diagnostics. Since 2006 she has been working as GMP inspector and since 2012 she has been working as Director of Inspection Department at the same Institute. As a Director of Inspection Department, she is responsible for the organization and management of supervision of manufacturers of veterinary medicinal product, medicated feedingstuffs, manufacturers of active substances, control laboratories, distributors and the activities connected with non-legal activities in the field of veterinary medicinal products. Another area of activity is also the organization of supervision of the handling of medicinal products, in particular by veterinarians, breeders, supervision of consumption of VMP, solving of quality defects of veterinary medicinal products. She is a member of working group E – commerce at the Ministry of Agriculture and the member of working group Market surveillance at the Ministry of Industry and Trade. Since the 2012 she is a member of the GMDP IWG Working Group, European Medicine Agency. Since 2012 she is a member of PIC/S Committee.

Brigitte Othmar-Vielitz

EMAV

Brigitte Othmar-Vielitz studied Biological Sciences at Edinburgh University and Göttingen University. She holds the Position of Qualified Person of Vaxxinova GmbH in Cuxhaven and has been head of Regulatory Affairs of Autogenous veterinary vaccines since 2014. She has 24 years of hands-on experience in the development and optimization of poultry vaccines from Master Seeds, batch manufacturing and testing to European wide registration. As part of her work at Lohmann Animal Health she also commented on legal texts and draft monographs.

She is member of the EMAV scientific working group and participated in the proposal for the new GMP regulations for autogenous vaccines presented by EMAV.

Biosketch

Dušan Palić

Dušan Palić

University Professor and Chair - Ludwig-Maximilians-University Munich, Faculty of Veterinary Medicine
Chair of Fish Diseases and Fisheries Biology
Address: Kaulbachstr. 37
80539 Munich, Germany
Tel: +49 89 2180 2282
Fax: +49 89 2180 992687
e-mail: d.palic@lmu.de

Professor Palić comes from a long line of veterinarians and educators, being the third generation Professor of Veterinary Medicine. He received D.V.M. and MVSc degrees from Faculty of Veterinary Medicine in Belgrade, Serbia, and Ph.D. from Iowa State University College of Veterinary Medicine. He is a founding member, certified aquatic veterinarian (CertAqV), and Past President of World Aquatic Veterinary Medical Association. Prof. Palić is also a founding diplomate of European College of Aquatic Animal Health (ECAAH).

He is the Director of the International Aquatic Veterinary Biosecurity Consortium and senior aquatic animal health expert for Food and Agriculture Organization of United Nations. He represented academia and organized aquatic veterinary profession in the FishMedPlus Coalition that was established by Federation of Veterinarians of Europe (FVE) upon request from European Medicine Agency (EMA), with the goal to improve access and availability of veterinary medical products, including vaccines, to the E.U. aquaculture industry.

On the global education front, Prof. Palić is member of the project team that is developing a model curriculum for day-1 competency in aquatic veterinary medicine. His daily work as Chair for Fish Diseases at LMU Munich includes research in innate immunity of aquatic animals, teaching aquatic veterinary medicine, as well as diagnostic and extension services.

Dietrich Rassow

CVO - Federal Ministry of Food and Agriculture
Germany

Dietrich Rassow is Head of the Animal Health and Welfare Directorate at the Federal Ministry of Food, Agriculture and Consumer Protection (BMEL), Chief Veterinary Officer (CVO) at international level and Delegate to the World Organisation for Animal Health (OIE). After studying in Berlin, practising and completing his state traineeship, Dr Rassow worked for 14 years in the state service of Lower Saxony. In 2004, he moved to the BMEL, where he headed various departments responsible for EU affairs, disease crisis management and international trade. Between 2012 and 2016, Dr Rassow was assigned as consultant to the World Organisation for Animal Health (OIE). In the Directorate headed by Dr Rassow, six departments deal with the topics of animal welfare, animal health, veterinary medicines, international trade and legal affairs.

Mariette Salery

Expert in Immunological Products - ANSES-ANMV
14 Rue Claude Bourgelat
Parc d'Activités de la Grande Marche
CS 70611
35302 FOUGERES FRANCE
Tel: +33 2 99 94 78 82
e-mail: Mariette.salery@anses.fr

Dr Mariette SALERY holds a DVM (2007, Toulouse, France) and a master level 1 in Cellular Physiology and Pathology (2006, Toulouse, France). She also followed advanced courses in biotechnology, immunology, cell biotherapy and statistics.

Before joining the ANSES-ANMV (French Agency for Veterinary Medicinal Products), she worked in New Caledonia as a coordinator in animal health programs for the local agriculture services.

She joined the ANSES-ANMV in 2009 and is now a senior assessor for Immunological products in the Scientific Department. She is involved in the assessment of Marketing Files for Immunological Products (quality, safety and efficacy parts) and in management of national and European procedures.
She was the Immunological Unit representative at the French Expert Groups for the Veterinary Medicinal Products from 2010 to 2013.

Until 2013, she serves as the French representative at the CMDv (Coordination Group for Mutual Recognition and Decentralised Procedures – Veterinary) where she is involved in the regulatory matters for immunological and pharmaceutical veterinary medicinal products.

Alain Schrumpf

DVM
GM Ceva Biovac - Ceva Biovac
6 rue Olivier de Serres
49070 Beaucouzé - France
Tel: +33 683847854
e-mail: alain.schrumpf@ceva.com

Biosketch

Ynte Schukken

Ynte Schukken

CEO - Royal GD
Arnsbergstraat 7
7418 EZ Deventer - the Netherlands
Tel: +316 10625040
e-mail: y.schukken@gdanimalhealth.com
www.gdanimalhealth.com

Dr Ynte Schukken is currently Chief Executive Officer at Royal GD in Deventer, the Netherlands and a Professor of Management of Farm Animal Health at Wageningen University with a courtesy appointment as Professor of Farm Animal Disease Control Programs at the Veterinary College at Utrecht University. Dr Schukken's research approach is based on understanding epidemiology and pathobiology of the diseases and population dynamics of infectious diseases in animal populations and in application of epidemiological, statistical and mathematical methods to animal disease research.

Royal GD is based in Deventer, the Netherlands and employs approximately 500 staff working in the laboratory, animal facilities or in the field. Royal GD operates one of the larger animal health laboratories in Europe, manages multiple disease control programs in the Netherlands and is also a CRO with a strong reputation, performing studies under GLP and GCP quality standards.

The animal health laboratory has a large pathology facility that is utilized by Dutch farmers and animal owners. The pathology facility is also the source of a large strain collection of both bacteria and viruses. Royal GD produces autogenous vaccines for its clients in the Netherlands.

Annie Sigognault-Flochlay

Director R&D, Qualified Person, Deputy General Manager - FILAVIE
20, La Corbière, Roussay
49450 - Sèvremoine
Tel: +33 6 85 14 19 02
e-mail: annie.sigognaultflochlay@filavie.com

Annie Sigognault Flochlay is currently Director of Research and Development, Deputy General Manager and Qualified Person at FILAVIE, an animal health company dedicated to the development and production of biological products for Europe and third countries markets, including viral and bacterial autogenous and classically produced veterinary vaccines.

Annie Sigognault Flochlay has worked in different international veterinary pharmaceutical companies for over 25 years, where she held various management roles in global project management, clinical development, international regulatory affairs, and vaccines manufacturing, in Europe and the US.

She has driven or edited multiple regulatory submissions and worked on successful development and production strategies, including CMC, for several global major products in animal health. She now focuses her work particularly on the development and production of new biological products for emerging viral diseases of livestock, for endemic pathogens in specific export countries, and for minor or orphan animal species.

Annie Sigognault Flochlay graduated from the National Veterinary School of Nantes in 1991 and holds a MSc degree in Biology. She lives in Angers, France.

Jason Todd

Head of GMP Inspections - Veterinary
Medicines Directorate (VMD)
Woodham Lane, New Haw, Addlestone,
Surrey - KT15 3LS, United Kingdom
Tel: +44 (0)1932 336911
e-mail: j.todd@vmd.gov.uk

I have a microbiology background originally specializing in this as part of my BSc degree. I then continued with a PhD at the University of Hertfordshire which focused on microbial culture and secondary metabolite production. After this, I took on a post-doctorate position at Kyushu University, Japan working on anaerobic fermentation as a means of biological waste treatment, before joining the VMD in 1997.

After a brief stint working on antimicrobial resistance issues, I transferred to the Biologicals Team where I was an inspector / assessor. I then took on the role of Manager of the Biologicals Inspection Team. The scope of inspections covered by the team was expanded from a focus on biological veterinary medicinal products, to cover all veterinary medicinal products in 2009 and I am now the VMD's Head of GMP Inspections with over 20 years' experience of inspecting manufacturers of authorized veterinary medicines and unlicensed veterinary treatments including products for administration under the veterinary cascade, equine stem cells and autogenous vaccines.

I am the VMD's representative at meetings of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) and the deputy chair of the PIC/S Veterinary Products Working Group.

Joris Vandeputte

President, IABS
Belgium

Joris Vandeputte was elected President of IABS (International Alliance for Biological Standardization) in June 2016. He is founding member of IABS-EU the European affiliate of IABS. IABS-EU implements the objectives of IABS at European level. IABS-EU is partner of the EU IMI (Innovative Medicines Initiative) projects ZAPI and VAC2VAC (www.IMI.eu, www.zapi-imi.eu, www.vac2vac.eu)

IABS hold its founding congress in Lyon in 1955. It is the global independent platform, interface, where stake-holders meet for exchange of science and issues related to vaccines, cell and gene therapy and human Biotherapeutics. IABS stimulates consensus building which might eventually be translated in regulatory frameworks and advises to decision makers.

Joris Vandeputte is also founder and president of TRIVAROP, a public affairs consultancy advising companies and associations in the area of global health-care. Joris has more than 40 years industry and international organisation's experience in vaccines, conceiving and developing vaccine policies at global level and towards developing countries in particular. Working with European institutions and policy-makers on innovation, health and development is his main activity.

Ewald Van Kuppeveld

Ripac Labor GmbH
Am Meuhlenberg 11
Tel : +49 331 581840-0
e-mail : info@vankuppeveldconsultancy.com
Ripac - Germany

Ewald van Kuppeveld is Pharmacist by training and working within the pharmaceutical industry for more than 30 years. During that time, he has been active at different positions like Qualified Person, Head of Production, Manager QA and Manager Operations mainly in the filed of aseptic manufacturing and vaccine production at a variaty of companies from start ups to large CMO's.

Nathalie Vassallo

Head of department and Qualified Person for autogenous vaccines production - LABOCEA
Zoopôle Le Sabot
7 rue du Sabot – CS 30054
22440 Ploufragan, France
Tel: +33296013722
e-mail Nathalie.vassallo@labocea.fr

Nathalie Vassallo is at the head of LABOCEA Departement of autogenous vaccines and Qualified Person for autogenous vaccines production since 2017. She joined LABOCEA in 1999, and worked in Immunology and Virology Department untill 2019.

Prior to that, she acquired 10 years of experience as veterinary pratictioner and technical manager for SmithKline Beecham Animal Heath.

LABOCEA is a public lab offering services and diagnostics in the field of animal health, plant health, food hygiene, hydrology and agri-environment, with an authorisation to produce autogenous vaccines.

Grégory Verdier

Head of Inspection Unit - French Agency for Veterinary Medicinal Products (Anses-ANMV)
14 rue Claude Bourgelat
Parc d'activités de la Grande Marche Javené
CS 70611
35306 Fougères - France
Tel: ++33 2 56 65 00 72
e-mail: gregory.verdier@anses.fr

Grégory VERDIER has been appointed head of inspection unit at the French Agency for Veterinary Medicinal Products on 1st June 2018.

Grégory VERDIER is a veterinarian, graduated in 1999 from the Toulouse Faculty of Medicine. After some years working in large animals and pets veterinary practice in different locations in France, he integrated the Directorate General for Food (DGAL) of the Ministry of Agriculture in order to reinforce the staff in the context of the BSE and scrapie disease outbreak. He spent one year at the National faculty for Veterinary health Services (ENSV) in Lyon in 2002-2003.

Then, he joined the French Agency for Veterinary Medicinal Products as a pharmaceutical inspector. Since 2003, he has been developing his expertise in several domains as Good Manufacturing Practices (chemical and immunological products), Good Distribution Practices, Good Pharmacovigilance Practices and Good Laboratory Practices. He is the Anses-ANMV representative in Europe Medicine Agency Good Manufacturing and Distribution Practices Inspection Working Group and in PIC/S committee. Since 2018, he has been chairing the PIC/S Working Group on Veterinary Medicinal Products.

Florian Voisin

Practitioner in pigs - Hyovet
5 PA Carrefour du Penthièvre
22640 Plestan, France
Tel: +33296307043
e-mail: accueil@hyovet.com

Florian Voisin is a DVM practicing swine medicine and applied research in the largest swine veterinary practice in France (HYOVET : 28 vets, working in partnership with COOPERL).

After his veterinary degree in 2003 Florian first worked 6 years as a swine practitioner in Brittany, France. Graduated in statistics applied to Clinical Research (2010), he worked 5 years as a full-time investigator in applied research for swine health and swine production science. Since 2014, Dr Voisin's current activity is to follow-up and monitor technical and economic performance of some of the members of the Cooperative. Advising continuously 2.700 farmers which produced over 5.7 million pigs in 2020, the veterinary practitioners of Hyovet are committed to ensure the profitability of each of the production units, targeting always the ROI and economic justification of the decisions, and focusing on the Best Practices applied, as well as on what has led the evolution of the pig industry in the recent years.

Gerfried Zeller

Managing Director - European Manufacturers of Autogenous Vaccines and Sera – EMAV – e.V.
Am Muehlbachbogen 63b
85368 Moosburg - Germany
Tel: +49 (0) 1522 8800579
e-mail: gerfried.zeller@outlook.de

Gerfried Zeller is a German veterinarian, graduated in Berlin. He was working in Senior Management positions in the Animal Health industry, like for Hoechst/ Intervet, Albrecht/Dechra and Merial/Boehringer Ingelheim, for many years.

Actually he's with Selectavet, a family owned Animal Health business in Germany, and is acting as consultant with focus on Animal Health, Life Science and Business Development for the industry and other stakeholders.

Since 2019 Gerfried Zeller holds the position as Managing Director of EMAV, the association of European Manufacturers of Autogenous Vaccines and Sera (www.emav.be). In this role he's coordinating the activities of the members from 12 European countries and is supporting the EMAV Board in the strategic positioning of manufacturing of Autogenous vaccines in a future common European market.

Gerfried Zeller is Chair of the German Academy for Animal Health (AfT), Bonn (www.aft-online.net) and president of the Society of Friends of Friedrich-Loeffler-Institut (FLI) - Federal Research Institute for Animal Health, Isle of Riems/ Greifswald