The Munich Seminar for Strategies and Product Development for Veterinary Medicinal Products - a great success

On 30 and 31st of January 2014, more than 50 attendees from 14 countries and 3 continents met in Munich at the Seminar on Strategies and Product Development of Veterinary Medicinal Products. The international panel of speakers covered all aspects of Product development: from the idea to marketing authorization and beyond.

The seminar was hosted by KLIFOVET AG, the leading product development organisation for regulated Animal Health and Nutrition products based in Munich, Germany. The General Manager of KLIFOVET AG, Dr Klaus Hellmann opened the seminar with an introduction to the current challenges facing the industry based on the changing environment of Animal Health Product Development in a consolidating industry and innovative environment. Dr Dieter Schillinger, former Head of Public Affairs Europe at Merial SAS and previously president of the German animal health industry association "Bundesverband für Tiergesundheit", now an independent animal health consultant chaired the seminar.

Dr Peggy Dillender, head of Bayer Animal Health's Global Business Development group located in Germany, provided an overview about what it takes to develop a product from the idea to market. In the following discussion Dr. Dillender gave advice for start-ups on what is required to partner with established global companies.

Dr Sergi Trilla, founder and CEO of Trifermed, a business services company based in London and Barcelona, offering project management for the development of Partnerships in Life Science, showed how thoughtful business modelling clarifies the role of potential partners and their value for an organisation and its customers.

Dr Beate Lohr, Head of Regulatory Affairs unit at KLIFOVET, presented on different regulatory options for Animal Health Products and discussed some critical points that may influence the decision for a regulatory strategy. She highlighted the importance of a thorough analysis before starting any development.

Dr Rik Nooteboom, Quality Manager and Qualified Person at Produlab Pharma, the Netherlands, focused in his presentation on the factors to be considered for successful outsourcing of manufacturing services and how to fulfil the requirements according the EU Good Manufacturing Practice requirements.

Dr Mirja Huhtinen, Head of Animal Health Clinical Research and Development at Orion Pharma, Finland, presented on the opportunities and obstacles of developing an approved human product for a veterinary application. She touched also the special role of minor use – minor species (MUMS) requirements in the development plan.

Dr Regina Wolf, Head of Product Development at KLIFOVET, Germany, provided an overview on the product development plan highlighting that most veterinary products are special and require an individual plan and considerations. She also emphasized that a regulatory SWOT and GAP analysis are useful tools as an aid to finally implement a realistic and customer adapted product development plan.

After these presentations a case study challenged the participants to find an appropriate regulatory procedure for a new veterinary medicinal product.

The seminar continued focussing on quality and safety aspects of product development.

Dr Rhona Duane, Irish Medicines Board, explained the view of a regulatory authority on quality aspects for pharmaceuticals providing an overview on the most important legislations and guidance.

Dr Eugenia Puentes, Director of Product Development of the Spanish biopharmaceutical group CZ Veterinaria discussed the quality aspects of product development specific for veterinary immunological products.

Dr Kevin Woodward, Senior Consultant with TSGE LLP, UK, presented on legal requirements including practical examples for establishing maximum residue limits (MRLs). Specific focus was set on the different approaches to calculate such MRLs based on the NOAEL and ADI.

Noel Joseph, Senior Safety Assessor at the Veterinary Medicines Directorate, UK, provided an overview on the legal framework of user safety assessment of Animal Health products. He explained the preparation of a User Risk Assessment and highlighted some of the most common mistakes observed.

Dr Holger Schmidt, founder of BioMedVet Research GmbH, a GLP accredited animal health CRO in Germany, provided an insight to target animal safety studies and their regulatory background.

The first day of the seminar concluded with at a networking dinner of original Bavarian cuisine after a short tour around the city centre of Munich.

On the second day the seminar continued with the safety aspects of product development.

Dipl. Ing. Anette Rudolf, Deputy of the Managing Director at LAUS GmbH, Germany, presented on the environmental risk assessment of veterinary medicinal products and their ecological and legal background.

Dr Corinne Philippe-Reversat, Senior Manager Regulatory Affairs at Merial, France, introduced the legal background, registration and production requirements for genetically modified organisms. She shared experience in leading such products through veterinary EU marketing authorization procedures.

Dr Tim Rowan, Rowdix Ltd. UK, started with his talk the session on efficacy aspects of product development. He provided a detailed overview on efficacy testing with a focus on dose selection and dose confirmation for veterinary pharmaceutical products.

Dr Regina Wolf, KLIFOVET AG, explained the efficacy aspects and the specific considerations for efficacy studies for vaccines and immunological products. Based on KLIFOVET's and her own experience she focused on the importance of well-established challenge models which serve as the primary source of the proof of efficacy while field studies need to confirm such results under commercial or field conditions.

These presentations were followed by a workshop where the participants were asked to briefly outline a development plan for a new product and identify possible obstacles on the way.
The afternoon session of the second seminar day concentrated on the submission and life-cycle management of an animal health product.

Gergely Hamar, Head of the Regulatory Affairs Directorate for Ceva-Phylaxia, Hungary, presented on the procedures and timelines of different authorization procedures for an initial marketing authorization application. He then focused more on Part I and II of the dossier and illustrated with examples the importance of building compliance into the dossier and the art of wording for the submission of a marketing authorisation for veterinary immunological products.

Dr Klaus König, Regulatory Affairs and Pharmacovigilance Consultant in Germany, previously heading the pharmacovigilance and regulatory affairs unit of Merial, Germany and as such also the working groups of the German animal health industry association, provided an overview on the pharmacovigilance system and the respective regulatory background highlighting differences in views among various EU countries assessing individual cases. He highlighted the need for a more harmonised approach by the veterinary pharmacovigilance inspectors.

Tobias Boldt, Head of Global Brand Management – Advantage family at Bayer Animal Health, provided an insight into what it takes to successfully launch a new veterinary medicinal product.

Dr Klaus Hellmann, General Manager at KLIFOVET AG completed the seminar program with a presentation on challenges and requirements of post marketing studies. He specifically addressed the issue of the legal justification of such studies in the light of the recently implemented EU directive 63/2010 and the different interpretation within the national legislation of EU member states.

Positive feedback was received from participants and speakers of the seminar alike and supported by statements such as “Let me thank you for the excellent conference we had last week in Munich. It will be for sure a significant help for us” and “I was very impressed of the high level of participation and the organization of the event” and thus confirming the excellent performance of the team and partners of KLIFOVET AG.

Klifovet AG is a highly specialised, full service provider of all services related to the development of animal health and nutrition products adding value to its customer’s performance. For more information on this and other animal health seminars please take a look at www.klifovet.com or write an e-mail to info@klifovet.com.

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