Association of Veterinary Consultants

KLIFOVET AG
ADDED VALUE TO ANIMAL HEALTH

# Conference on International Regulation of Animal Health Products

## October 11th, 2019 Maritim Hotel Munich (near main station)

| Time | Topic | Presenters |
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| 08:30 | Registration and Snacks | |
| | CHAIR: | Tim Rowan, Rowdix, UK |
| 09:00 | Conference Opening and Introduction<br><br>The current situation of the Animal Health Industry | Alessandro Agostini (President of AVC, IT)<br>Klaus Hellmann<br>(CEO at Klifovet AG, Germany) |
| 09:15 | Overview of the current EU regulation and technical requirements for veterinary pharmaceutical products<br>▪ EU procedures, agencies, and roles<br>▪ Technical requirements, guidelines, and scientific advice<br>▪ MRL's (Maximum Residue Limits), withdrawal period, and MUMS (Minor Use Minor Species) rules | Anja Holm<br>(CEO at Central VetPharma Consultancy, Denmark) |
| 10:00 | Regulation of Feed Additives in the EU<br>▪ Brief history of EU feed additive legislation<br>▪ Role of EU Commission, EURL & EFSA<br>▪ Feed additive categories & dossier structure | Elinor McCartney<br>(President at Pen&Tec Consulting, Spain) |
| 10:30 | The new VMP regulation in EU with special focus on biologicals<br>▪ Changes to the procedure for MA<br>▪ Definitions of terms and consequences<br>▪ Novel therapies<br>▪ Any other news public by that day | Klaus Hellmann<br>(CEO, Klifovet AG, Germany) |
| 11:15 | Coffee Break | |
| | CHAIR: | Alessandro Agostini, G.A.B.A. srl, Italy |
| 11:45 | Current regulations on VMP and FA in Russia and the countries of EEU<br>▪ Scheme of registration and duty of drugs and immunobiological in Russia and the countries of the Eurasian Economic Union (EEU)<br>▪ Registration scheme of feed additives in Russia and the countries of the EEU. Features registration coccidiostatics<br>▪ Principles of registration of veterinary drugs and immunobiological in the EEU<br>▪ Scheme for obtaining GMP certificate of Russia | Nina Kiryukhina<br>(Owner at VetRegister LLC, Russia) |
| 12:30 | Current regulations on VMP in Japan<br>▪ Overviews of Japanese animal health markets, multinational affiliates, domestic companies, pharmaceuticals and biologic products<br>▪ Overviews of regulatory requirements of animal health products in Japan<br>▪ Reviewing process of NADA and ANADA<br>▪ Schemes to shorten local development time line | Eiji Fuku<br>(Managing Director at ALVIS Inc., Japan) |
| 13:15 | Lunch Break | |
| | CHAIR: | Klaus Hellmann, Klifovet AG, Germany |
| 14:00 | Current regulations on VMPP in Brazil and South America<br>▪ TBD<br>▪ TBD<br>▪ TBD | Byron Silva (Head Consultant at Vet Affairs, Brazil) |
| 14:45 | Current regulations on VMP in West African countries<br>▪ WAEMU procedures for the Marketing Authorisation (MA) and pharmacovigilance;<br>▪ Scheme of MA procedures and fees<br>▪ New regulations: requirements and analytical protocol, safety tests, pre-clinical and clinical tests<br>▪ New decision establishing the procedure for MA application (MAA) | Rimma Ishimbaeva<br>(Consultant, France) |
| 15:15 | Coffee Break | |

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| | CHAIR: | Tim Rowan, Rowdix, UK |
| 15:45 | Registration of Animal Health Drugs in the USA - a user guide to managing the law, processes, science and people<br>▪ Working with FDA CVM<br>▪ Managing Regulatory Processes, Guidelines, Innovation and Interactions | Ed Robb<br>CEO, BioPharmaPotentials, USA |
| 16:30 | Current Regulation on VMP in Saudi Arabia and other Middle East countries<br>▪ TBD<br>▪ TBD<br>▪ TBD | Akram Ahmed Hatem<br>RA Manager EEMEA at Bayer AH GmbH,Germany |
| 17:15 | Q&A and closing of conference | |
| 19:00 | Networking drinks and dinner | All participants and AVC members |