7th VICH Conference

VICH and a new era

Programme

13–14 November 2024

EMA

Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Registration desk: will be open 16:00 – 19:00 12th November 2024

DAY 1 – 13 November 2024

08:30-16:00	***Registration open***
9:00-9:20	***Session 1: Welcome and Opening:*** Moderator: Nick Jarrett, VICH Coordinator for EU, EMA - **Welcome and Opening** (20') Eva Zamora, Directorate-General for Health and Food Safety, European Commission Emer Cooke, Executive Director, EMA Rick Clayton, AnimalhealthEurope
9:20-10:40	***Session 2: Keynote Addresses*** Moderator: Javier Yugueros-Marcos, Head of Department, Antimicrobial Resistance and Veterinary Products Department WOAH - **Why WOAH is a strong advocate of VICH** (20') Maria Szabo, Scientific Coordinator, WOAH - **How is VICH responding to global needs in a new era?** (20') Matthew Lucia, Director, Office of New Animal Drug Evaluation, CVM, FDA - **VICH achievements** (20') Hervé Marion, VICH secretariat **Q&A session** (20')
10:40-11:10	***Coffee break***
11:10-12:30	**Session 3: VICH moving forwards** Moderator: Mariko Ochiai, Chief Inspector, JMAFF - **Restructuring (and future vision?)** (20') Shoko Iwamoto, Executive Research Officer, JMAFF - **VICH workplan** (20') Margaret Churchill, Executive Director, South African Animal Health Association - **The view of a VICH Forum member** (20') Yuriy Kosenko, SCIVP, Ukraine **Q&A session** (20')
12:30-14:00	***Lunch***
14:00-15:15	**Session 4: How VICH guidelines are developed, implemented and used** Moderator: Nina Walser, Head of Division Swiss Medic, Switzerland - **How VICH guidelines are developed, implemented and used** (15') Include perspective of standing member Brigitte Boenisch, Head of RA Business Operations, Boehringer-Ingelheim Animal Health - **How VICH guidelines implement the 3Rs in safety studies** (15') Esther Werner, Deputy Head, Division of Veterinary Medicine, Paul-Ehrlich Institute, Germany - **Challenges and perspectives in adopting VICH guidelines in VICH Forum countries/regions and how to overcome them.** (15') Adelaide Ayoyi, MRP Coordinator, East African Community, Tanzania **Panel discussion** (20')
15:20-15:45	***Coffee break***
15:45-17:00	**Session 5: Scientific issues** Moderator: Johan Schefferlie, CVMP Chair, EMA, EU - **Scientific topic 1: Safety of monoclonal antibodies** (20') Catrina Stirling, Associate Director Regulatory Affairs, Zoetis - **Scientific topic 2: Pharmacovigilance and signal management** (20') Kathrin Schirmann, EU Signal Detection Advisor, Bundesamt für Verbraucherschutz und Lebensmettelsicherheit (BVL), Germany - **Scientific topic 3:- bioequivalence and dissolution testing** (20') Marilyn Martinez Senior Biomedical Research and Biomedical Product Assessment Service Expert, CVM, FDA **Q&A session** (15')
17:00-17:10	Close of day 1 and house-keeping (R. Clayton)
18:0022:00	***Gala dinner***

DAY 2 – 14 November 2024

08:30	*Registration open*
9:00-10:15	**Session 6: New or revised VICH GLs** Moderator: Kaoru Eguchi, Executive Research officer, JMAFF - **GL topic 1: anthelmintics** (20') Aimee Phillippi-Taylor, Veterinary Medical Officer, Center for Veterinary Medicine, Food and Drug Administration, USA - **GL topic 2: Good manufacturing practice for active pharmaceutical ingredients** (20') Mai Huynh, Supervisory Chemist, Center for Veterinary Medicine, Food and Drug Administration, USA - **GL topic 3: pharmaceutical development** (20') Mai Huynh, Supervisory Chemist, Center for Veterinary Medicine, Food and Drug Administration, USA **Q&A session** (15')
10:15-10:45	*Coffee break*
10:45-12:15	**Session 7: Opportunities from international guidelines and regional collaborations** Moderator: Alice Sigobodhla, Head of Veterinary Medicines Unit, South African Health Products Regulatory Authority - **International collaborations** (20') Marilena Bassi, Director General, Veterinary Drugs Directorate, Health Canada - **GMP Inspections Reliance Programmes and Mutual Recognition Agreements** Gregory Verdier, GXP Inspector and Chair of PIC/S QG on veterinary medicinal products, ANSES, France and Piotr Krauze, Senior Scientific Specialist – GMP International Agreements, EMA - **Regional collaboration and mutual reliance** (20') Innocent Ravengai, BOMRA, ZAZIBONA **Panel discussion** (up to 30')
12:15-14:00	*Lunch*
14:00-15:20	**Session 8: Technical challenges** Moderator: Erik de Ridder, Director Global Regulatory Affairs Strategy and Policy, Elanco Animal Health - **New science in veterinary biologics** (20') Kota Sato, Senior Research officer, JMAFF and Chair of Biologicals Expert Working Group - **New science and reduction in the use of experimental animals** (20') Sarah Adler-Flindt, EMA 3Rs Working Party Vice-Chair, Bundesamt für Verbraucherschutz und Lebensmettelsicherheit (BVL), Germany - **Real world evidence and big data** (20') Ricardo Carapeto, Head of Area Environmental Risk Assessment, Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), Spain **Q&A Session** (20')
15:20-16:40	**Session 9: The future** Moderator: Donald Sibanda, APVMA, Australia - **The expectations from a VICH Forum member** (20') Barbara Borges Cordeiro, Ministry of Agriculture and Livestock, Brazil - **Inspired by VICH: International Forum on in vitro diagnostics** (20') Jennifer-Christelle Essolomwa, Regulatory Affairs Officer, HealthforAnimals - **Supported by VICH: Regulatory convergence** (20') Carel du Marchie Sarvaas, Executive Director, HealthforAnimals - **The Vision for the future** (20') Ivo Claassen, Head of the Veterinary Medicines Division and Deputy Executive Director, EMA, Chair of the 43rd VICH Steering Committee Meeting
16:40-16:55	**Conclusions of the Conference** (15') Rick Clayton, Technical Director, AnimalhealthEurope
16:55-17:05	**Closure of the Conference** (10') Ivo Claassen, Head of the Veterinary Medicines Division and Deputy Executive Director, EMA, Chair of the 43rd VICH Steering Committee Meeting