



7th VICH Conference
VICH and a new era

Programme



NOV 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 WOAHA - Why WOAHA is a strong advocate of VICH (20') Maria Szabo, Scientific Coordinator, WOAHA - 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 Lebensmittelsicherheit (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)
18:00-22:00	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 <ul style="list-style-type: none">- 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 <ul style="list-style-type: none">- 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 <ul style="list-style-type: none">- 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-Flint, EMA 3Rs Working Party Vice-Chair, Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (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: D. Sibanda, APVMA, Australia <ul style="list-style-type: none">- 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