

VICH Steering Committee

(Chairperson rotates among the three full member regions,
in accordance to the location of the meeting)

Introduction

VICH consists of a Steering Committee (SC) responsible for decisions and governance of the process and Expert Working Groups (EWG) responsible for technical input. The VICH Steering Committee is the driver of the harmonisation process. The Steering Committee is the only structure that is empowered to take decisions such as selecting topics, releasing draft guidelines for consultation and adopting final guidelines for implementation in the three regions. The SC is also responsible for the organisational charter of VICH and for establishing the VICH Strategy and Work Programme. The VICH SC meets every 12 months; the location of meetings alternates between Japan, the EU and the US. The VICH SC also has annual on-line meetings at the 6-month half-way point.

VICH Founding members (2 delegates plus 1 coordinator per Founding Member)

The Founding members are USA, Japan and EU. Each Founding Member may appoint two delegates and one coordinator to act as contact point with the VICH secretariat. The coordinators can actively participate in SC meetings but have no voting rights. Founding members are obligated to implement all VICH guidelines.

Standing members (1 delegate per standing member)

The regulatory authorities and the industry associations from Australia, New Zealand, Canada, South Africa and UK, are standing members to VICH. Standing members participate in SC meetings and have the opportunity to take part in the discussion, but they do not have a vote and do not sign-off any draft or final guideline. Standing members are obligated to implement VICH guidelines to 'the fullest extent possible'.

Observer members (1 delegate per observer member)

An interested party can request to attend the VICH SC meetings without participating in the discussions or intervene, unless invited by the chair. The Observer members are currently Swissmedic and scienceindustries (Switzerland). The Association of Veterinary Biologics Companies (USA) is an Interested Party. Invited VICH Forum members can also observe VICH SC meetings.

The role of the WOA

WOAH provides support to VICH and encourages its member countries to take into consideration the VICH guidelines. WOA promotes the VICH international harmonisation process for the marketing authorisation of veterinary medicines as a necessity to support animal health, public health and facilitation of international trade. In order to provide WOA member countries with full information about the VICH harmonisation efforts, WOA circulates relevant VICH documents to WOA member countries for comments and circulates final VICH guidelines.

The role of the Steering Committee

- Identify existing gaps where the development of VICH guidelines could produce a benefit for all members;
- Determine the working procedures;
- Determine the priority work items based on concept papers prepared by its members;
- Set up the appropriate Expert Working Groups (EWGs) and appoint topic leaders and EWG chairpersons;
- Consider and resolve issues raised by the EWGs;
- Approve the draft recommendations issued by EWGs before release for world-wide consultation and subsequently for approval by the regulatory authorities of the Founding Members (EU, Japan and the USA);
- Take responsibility for monitoring the maintenance and review of VICH guidelines;
- Agree assignments at the end of the SC meeting recorded in an actions table with deadlines.

New topics

The Steering Committee defines a priority item from a concept paper sponsored by one of its members. An EWG is established and a topic leader is appointed to take charge of drafting a guideline within a clear scope and mandate.

The SC members ensure that each expert is properly briefed and has a clear mandate enabling him/her to meet the expected outcome in the timeframe defined by the SC, in accordance with established VICH guidance; and ensure that each topic leader has the required competence and skills to lead an EWG and achieve its objectives.

Steering Committee Composition

Founding Members: C. Lowney and E. Norton (AHI), J. Schefferlie and E. Zamora Escribano (EU), B. Boenisch and E. De Ridder (AnimalhealthEurope), K. Tuchiya and H. Chee (JVPA), K. Eguchi and S. Iwamoto (JMAFF), M. Lucia and G. Srinivas (US FDA and USDA)

Coordinators: R. Cumberbatch (AHI), N. Jarrett (EU), R. Clayton (AnimalhealthEurope), M. Ochiai (JMAFF), K. Oishi (JVPA), B. Robinson (FDA/USDA)

Standing Members: D. Sibanda (APVMA), C. Bennett (AMA), E. Tatone (Health Canada), C. Filejski (CAHI), K. Booth (MPI NZ), J. Howe (APHA NZ), M. Churchill (SAAHA), A. Sigobodhla (SAHPRA), D. Murphy (NOAH UK), S. Eckford (VMD UK)

Observers: L. Nagao (AVBC), N. Walser (SWISSMEDIC), Y. Käser (SCIENCEINDUSTRIES, Switzerland) WOA: M. Szabo and L. Le Letty (ANSES)

Secretariat: C. Du Marchie Sarvaas and H. Marion (HealthforAnimals)



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