

ACTIVITIES OF VICH

– BACKGROUND AND ACHIEVEMENTS –

BACKGROUND OF INTERNATIONAL HARMONISATION OF VMPS

- **1992: International Technical Consultation on Veterinary Drug Registration (ITCVDR)**

- OIE was required the rule of harmonisation of approval standards for VMPS

- **1993: OIE General Session**

- Decision to Establish ad hoc group
- Confirm that we will focus solely on the harmonization of technical requirements

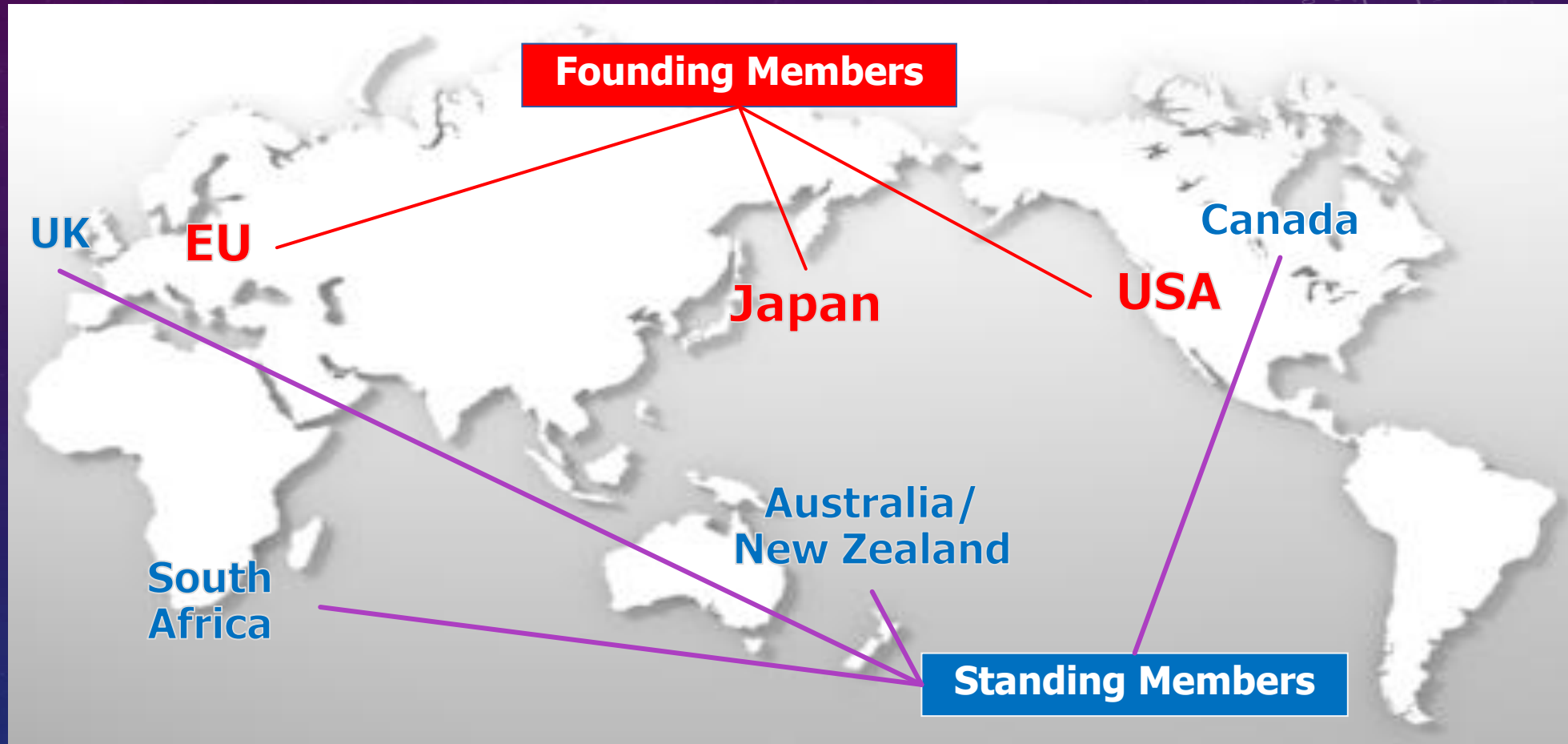
INTERNATIONAL HARMONIZATION OF HUMAN MEDICINES

- 1980s: promoting international harmonization of various regulations among countries
- 1990: preparations are underway following bilateral consultations among Japan, the U.S., and Europe
- 1991: First ICH Meeting
- ICH: International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

ESTABLISHMENT OF VICH

- 1996: First Steering Committee(SC) meeting
OIE HQ in Paris
- VICH Organisational Charter
 - Reflecting the working group's proposals
 - Maintaining the basic framework to date

VICH MEMBERS/REGIONS



WOAH : Associate Member, HealthforAnimals: Secretariat

VICH MEMBERS/REGIONS

Area	Regulator	Industry
JAPAN	JMAFF	JVPA
US	US FDA – Center for Veterinary Medicine, USDA – Center for Veterinary Biologics	US Animal Health Institute
EU	European Commission, European Medicines Agency	AnimalhealthEurope

EXPERT WORKING GROUPS

- Quality EWG
- Biologicals EWG
- Pharmacovigilance EWG
- GRDF EWG
- Safety EWG
- Combination product GLs EWG
- Bioequivalence EWG
- Metabolism and Residue EWG
- Medicated premixes EWG

IMPLEMENTATION OF GLS

<Achievements>

- More than 50 VICH guidelines have been developed.
- Implemented domestically through Director-General's notifications issued by NVAL.
- Studies conducted in accordance with VICH guidelines can be used directly for marketing authorization applications.
- Reduction in timelines : Shorter time to submission Shorter review timelines.
- Reduction in animal testing, contributing to animal welfare considerations.
- Developed through collaboration among experts worldwide Achieving an appropriate balance between scientific rigor and regulatory requirements for VMPs.
- Contributing to improvements in the quality, efficacy, and safety of VMPs.

NEW DEVELOPMENTS AT VICH

- Emergence of Emerging.
- Economies Explosive growth in pharmaceutical manufacturing capacity and global distribution.
- Ensuring the quality and safety of medicinal products can no longer be achieved solely through regulatory control in developed countries.

→ VICH Forum

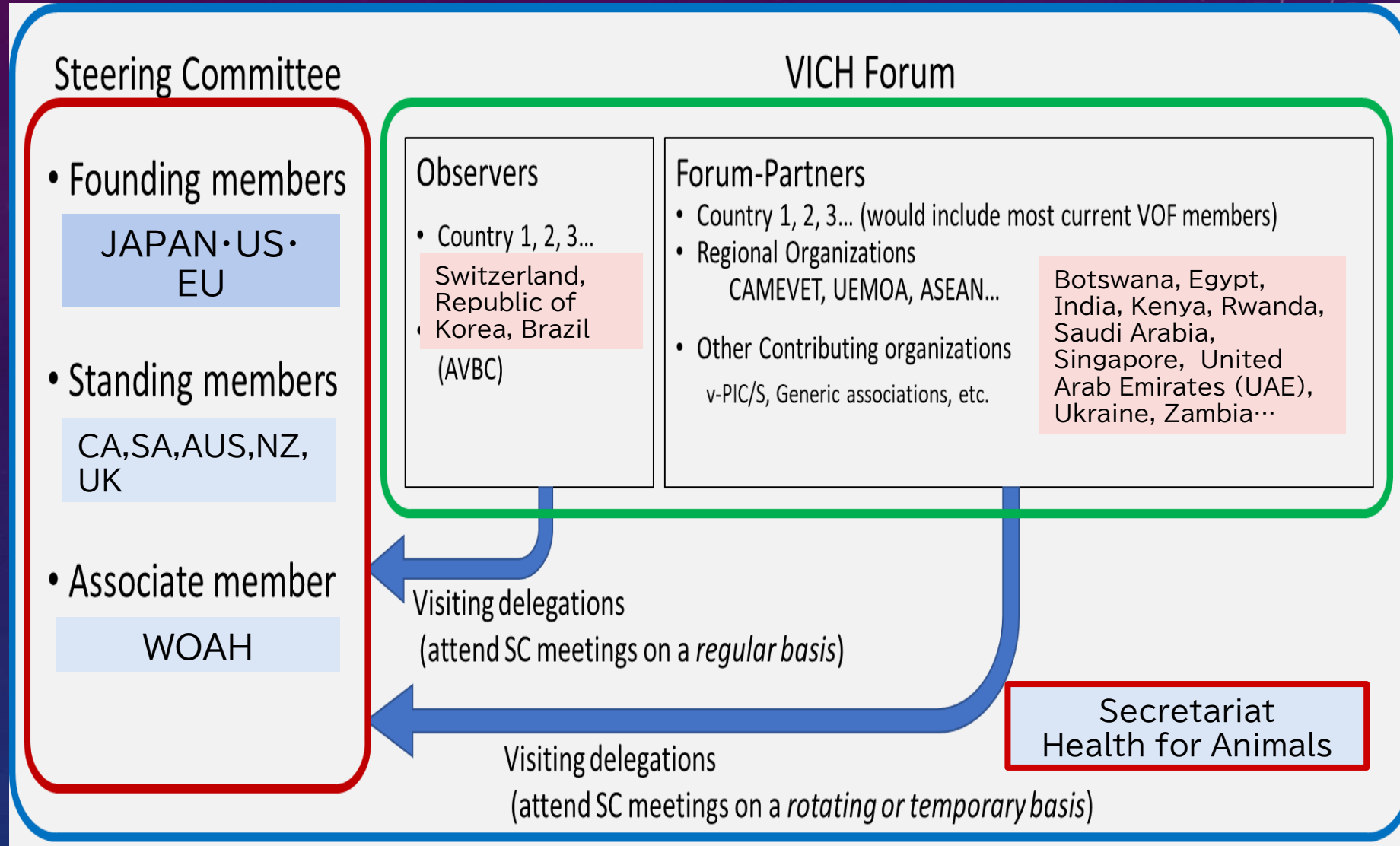
VICH FORUM

- A platform for information exchange to promote the dissemination of VICH guidelines to countries outside the VICH participating regions (Japan, US, EU, etc.).
- Under the leadership of WOAHA, the VICH Forum is co-chaired by VICH and WOAHA, with discussions organized around selected thematic issues.
- Held 18 times since June 2012 (held in conjunction with VICH Steering Committee (SC) meetings).

【Topics in 2025】

- Regulatory challenges faced by individual countries and responses to adverse events.
- Regulatory frameworks for innovative VMPs.
- Training on bioequivalence and biowaivers.
- Training on the regulation of Biologicals by VICH founding members.

VICH BODY





SC meeting VF meeting
2026 NOV 16-19th @Tsukuba city, JAPAN