Workshop for OIE National Focal Points on Veterinary Products

Casablanca, Morocco, 6-8 December 2011

VICH

Structure and Organisation

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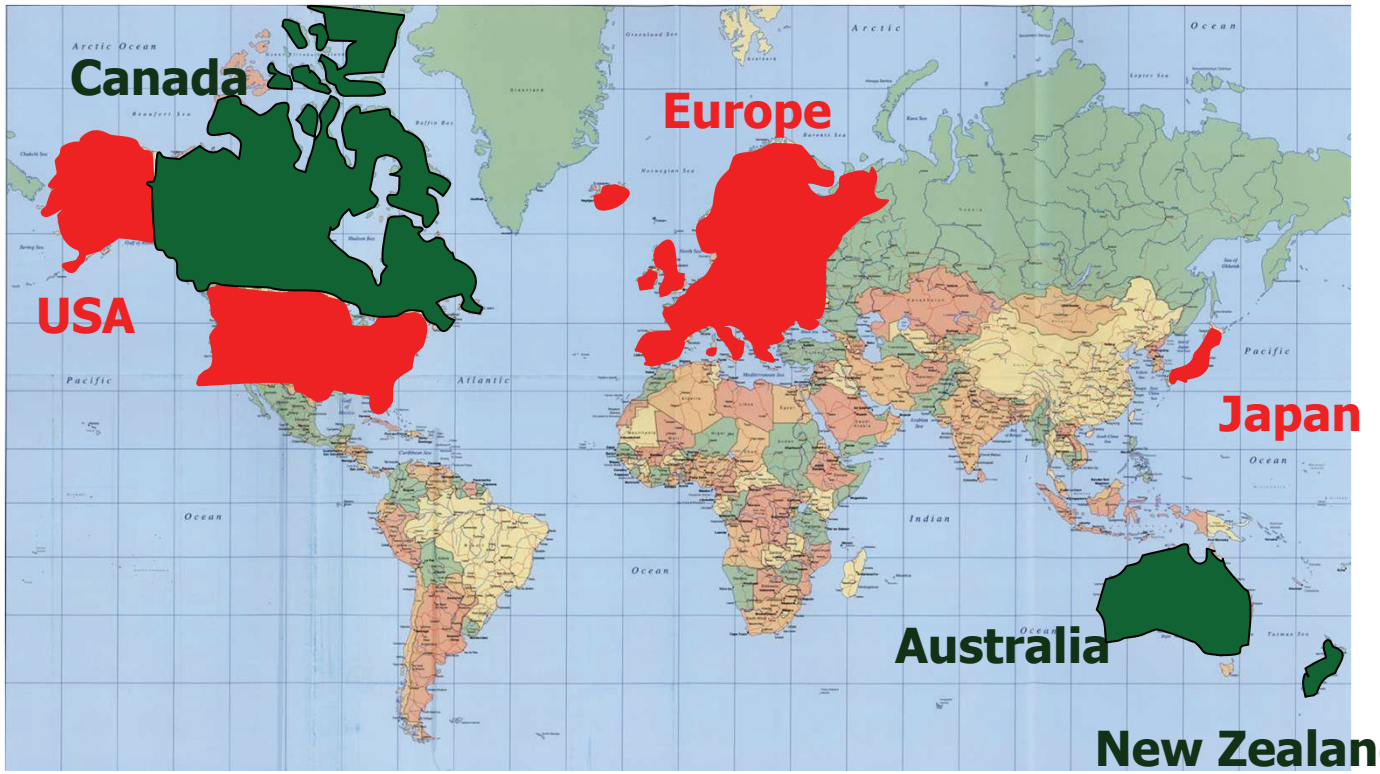
IFAH

What is VICH?

VICH =
International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

- International tripartite cooperation programme
- Brings together Regulatory Authorities and Industry

The VICH Regions



= VICH member,

= VICH observer

Developing VICH

1991	Creation of ICH with 1st conference
1992	7th ITCVDR conference in Argentina: concept of VICH
1994	OIE ad hoc group: scope, membership and objectives of VICH
10-11 April 1996	1st VICH Steering Committee in the OIE Offices in Paris – *VICH takes up work*
Nov. 1999	1st VICH Public Conference in Brussels (Europe)
Oct. 2002	2nd VICH Public Conference and 11th Steering Committee meeting in Tokyo (Japan)
Oct. 2004	Adoption of the VICH Strategy for 2006-2010
May 2005	3rd VICH Public Conference and 16th Steering Committee meeting in Washington DC (USA)
June 2008	First reflection on Global Outreach
June 2010	4th VICH Public Conference , 24th Steering Committee and plenary exchange on Global Outreach Strategy in the OIE Offices in Paris (Europe)

VICH Objectives

- Establish and implement harmonized regulatory requirements for veterinary medicinal products in the VICH Regions, which meet high* quality, safety and efficacy standards and minimize the use of test animals and costs of product development

  ⇨ VICH Guidelines

- Monitor and maintain existing VICH guidelines, taking particular note of the ICH work program and, where necessary, update these VICH Guidelines

  ⇨ VICH revised Guidelines

* *But not necessarily the highest possible*

VICH Objectives

- Ensure efficient processes for maintaining and monitoring consistent interpretation of data requirements following the implementation of VICH guidelines

- By means of a constructive dialogue between regulatory authorities and industry provide technical guidance enabling response to significant emerging global issues and science that impact on regulatory requirements within the VICH regions

VICH Objectives

- Greater harmonisation of requirements for veterinary product registration
  - Reduced/eliminate need for duplicate testing
  - More efficient use of human, animal and material resources while safeguarding quality, safety & efficacy
  - Reduction of unnecessary delays in global product development
  - Provide a basis for wider international harmonisation of registration requirements

⇨ **VICH Outreach – Forum agreed**

Members of VICH SC

- Regulatory Representatives from:
  - EU ➔ EMA + European Commission
  - JAPAN ➔ JMAFF
  - USA ➔ FDA-CVM + USDA-CVB
  - ANZ ➔AVPMA + NZFSA
  - Canada ➔HC-VDD + CFIA-VBS
- Representatives from Regional Industry Associations:
  - AHI, JVPA, IFAH-Europe, Animal Health Alliance, AGCARM, CAHI
- OIE - Associate Member
- Secretariat: IFAH

Role of VICH/OIE/Codex

- **VICH** develops harmonised data requirements, i.e. standards for the scientific studies on quality, safety and efficacy that are required to obtain a marketing authorisation of a veterinary medicinal product

  ⇨ VICH Guidelines

- **OIE** develops health standards for international trade in animals and animal products that member countries can use to protect themselves from the introduction of diseases and pathogens, without setting up unjustified sanitary barriers

  ⇨ OIE normative documents

- **OIE** also improves the legal framework and resources of national Veterinary Services

Role of VICH/OIE/Codex

- **Codex Alimentarius,** the Joint FAO/WHO Food Standards Programme develops international food safety standards, such as
  - Codes of practice, Guidelines
  - Maximum residue limits (MRLs) for residues of veterinary drugs in foodstuffs of animal origin:
    proposed by the Joint FAO/WHO Expert Committee of Food Additives (JECFA),
    recommended by the Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF),
    adopted by the Codex Alimentarius Commission (CAC)

    ⇨ Codex food safety standards

The VICH Process

- The **VICH Steering Committee** drives the process: selects topics, releases draft guidelines for consultation, and adopts final guidelines for implementation
- **VICH Expert Working Groups** bring together the specific expertise for guideline development
- **Transparent guideline development** through the VICH 9-step process, public website and conferences
- **Commitment:** VICH members have committed to implement VICH guidelines in their veterinary product regulatory processes, VICH observers voluntarily do so

The VICH Process

- Thorough selection of topics by the Steering Committee: assessment of benefit to human and animal health through greater harmonisation, and resource management
- Work mandated by Steering Committee to Expert Working Groups
- Elaboration and adoption of guidelines in a 9-step procedure
- Follows closely ICH, taking account of specific veterinary needs
- Consequent need for maintaining and updating existing GLs on a regular basis

The VICH Process

VICH Steering Committee

Secretariat (IFAH)

Expert Working Groups

Quality EWG

Safety EWG

MRK* EWG

ESI+ EWG

Bioequivalence EWG

Biologicals EWG

Microbiological ADI EWG

* Metabolism and Residue kinetics + Electronic Standards Implementation

OIE

The VICH process: 9 step procedure

Step 1	▪ Concept paper to propose issue ▪ Review by SC ▪ Appointment of Topic Leader/Chairman
Step 2	EWG to produce draft Guideline
Step 3	SC to review draft Guideline
Step 4	Public consultation in the regions
Step 5	EWG to review comments
Step 6	SC to adopt final Guideline
Step 7-8	Implementation of Guideline
Step 9	Recommendation for review
→	9 step procedure

The VICH Process

- Programme runs in cost-effective & transparent manner
  - All participants pay their own way
  - Industry associations host events & meetings
- Regulators and OIE ensure wide circulation of draft GLs for a 6-months consultation period
- Expert Working Groups meet regularly to progress their work
- Steering Committee meets at regular intervals
  - Monitors and supports Expert Working Groups
  - Monitors implementation in the Regions

The VICH Process

The VICH language is English

- ✓ All meetings are run in English, whether Steering Committee or Expert Working Groups (translation is organised at own cost – currently for Japan)
- ✓ All documents (drafts and final) are written in English only
- ✓ VICH members may translate the documents in their national language at their own cost

The VICH Process

- The Steering Committee meets regularly,
  - ✓ Every 8 to 9 months, adjusted to need
  - ✓ Rotation between the 3 regions (EU – USA - Japan)
  - ✓ A representative from the regulators from the host region chairs the meeting
  - ✓ Monitors and supports the Expert Working Groups
  - ✓ Monitors implementation of Guidelines in the regions
- Expert Working Groups also meet regularly to progress their topics, subject to Steering Committee approval

VICH Guidelines

- VICH guidelines provide harmonised guidance that describes the data to be provided in an application dossier for a marketing authorisation for a veterinary medicinal product
- VICH also establishes guidelines on the pharmacovigilance for veterinary medicinal products, i.e. the requirements for their post-marketing safety monitoring
- VICH does not normally develop guidance on how to carry out the assessment of the data or on the assessment approach
- Assessments are done by the regulatory authorities of the VICH countries and regions

Achievements

15 years of confidence building and collaboration!

- Considerable improvements of harmonization of data requirements between participating regions, thus
  - ✓Reduction of animal testing
  - ✓Reduction of costs
- Better understanding of regulations and concerns in the other regions
- Unique discussion forum between acknowledged scientific experts from Regulatory Authorities and Animal Health Companies
- New: VICH Outreach Forum to better involve non-member countries, 1st meeting in June 2012, Brussels

Achievements [2]

- **Decisions in the SC and the EWGs by consensus**
- Unique opportunity for regulators and industry to discuss topics openly enabling a pooling of expertise to jointly draft guidelines on regulatory data requirements
- Opportunity to update regional standards
- Global product development approach
- Accelerate Veterinary Medicinal product development for Livestock & Companion Animals
- Increased uniformity of regulatory process and technical requirements
- Increase availability of Veterinary Medicines
- Increased Product Safety and Consumer Safety

Achievements [3]

- Reduction of animal-based tests – commitment to the "3 R" (Reduce – Refine – Replace)
- Reduction in number of animals used (Safety)
- Regulatory Agencies implement in the 5 regions ➔ Official publication – change of regulatory requirements/legislation
- Excellent scientific expertise
- VICH guidelines on data requirements for registration of veterinary medicines (more details follow)
  - 47 finalised VICH Guidelines (of which 6 revised)
  - 10 new VICH Guidelines under development

Achievements [4]

- 47 finalised guidelines (GLs):
  - Implemented: 42
  - For implementation in 2012: 5
- New GLs under consultation/discussion: 10
- Revised GLs at step 9
  - Implemented: 6
  - Under review: 1
- Detailed list of GLs available on the website

Achievements [5]

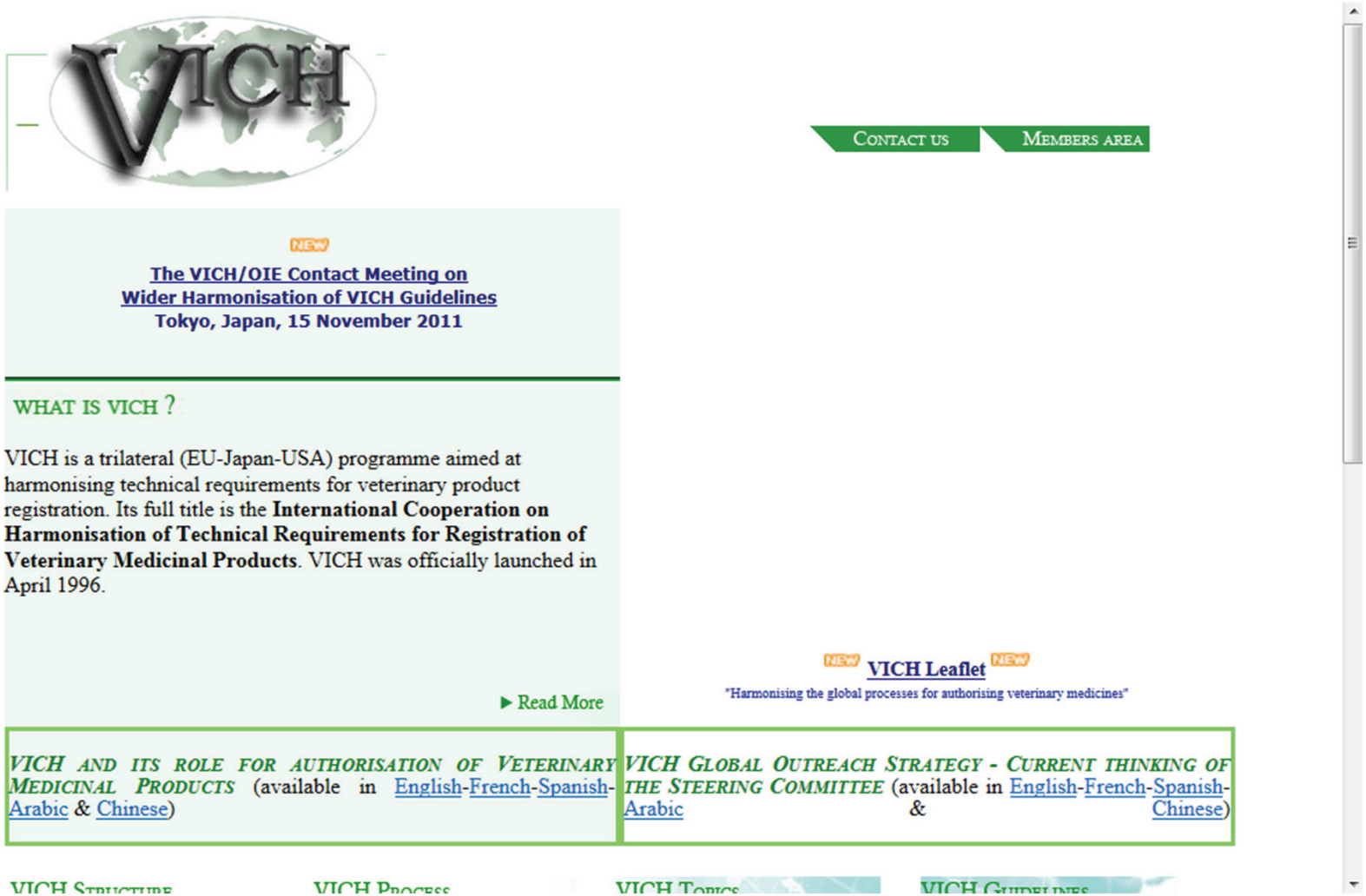
New GLs under discussion/consultation:

- 3 Pharmacovigilance GLs
- 1/2 Biological GLs
- 1 Safety GL
- 1 Bioequivalence GL
- 1 Metabolism & Residue Kinetics

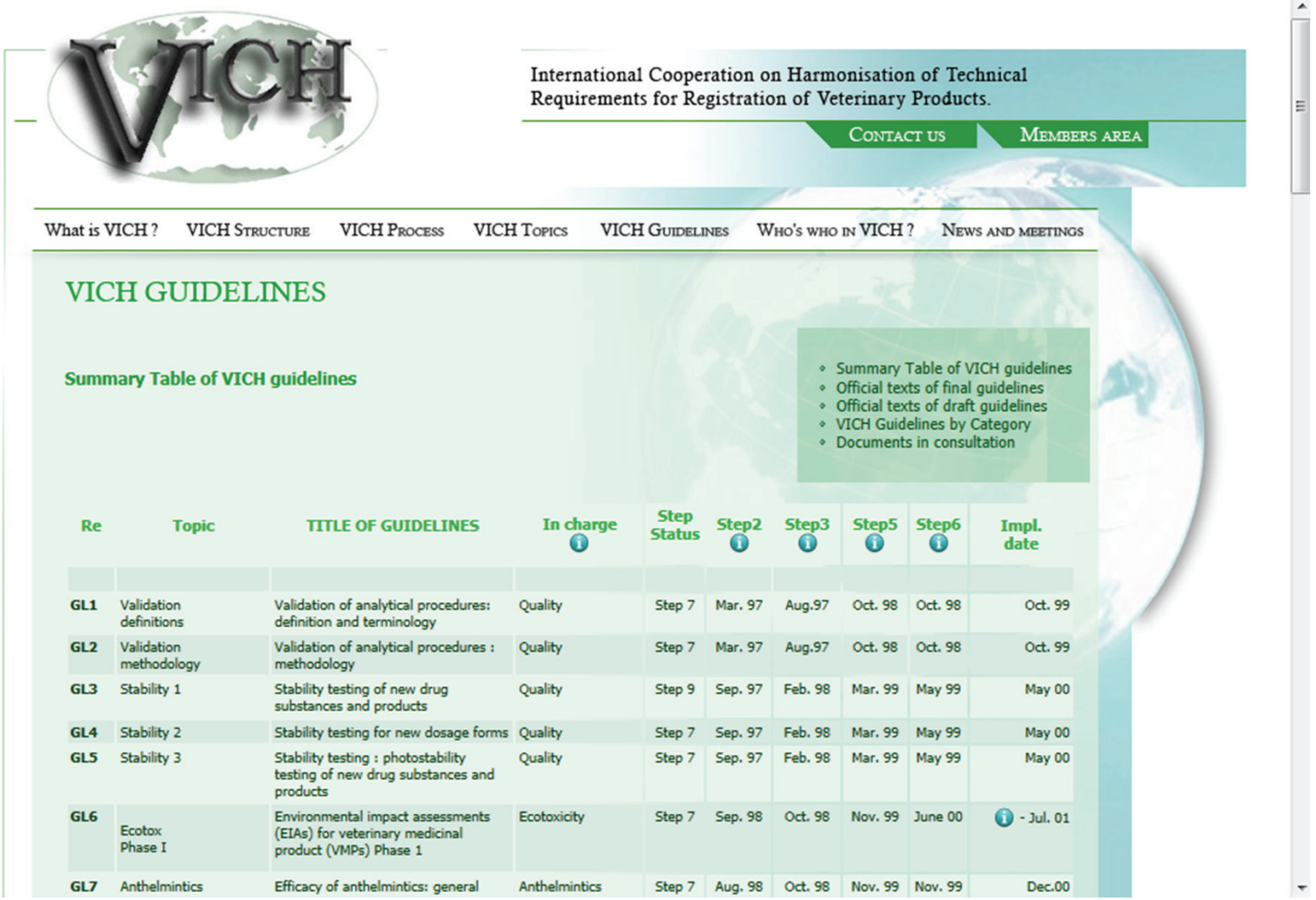
Final GL under Revision:

- 1 Quality GL

The VICH website



The VICH website



International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products.

CONTACT US | MEMBERS AREA

What is VICH ? | VICH STRUCTURE | VICH PROCESS | VICH TOPICS | VICH GUIDELINES | WHO'S WHO IN VICH ? | NEWS AND MEETINGS

VICH GUIDELINES

Summary Table of VICH guidelines

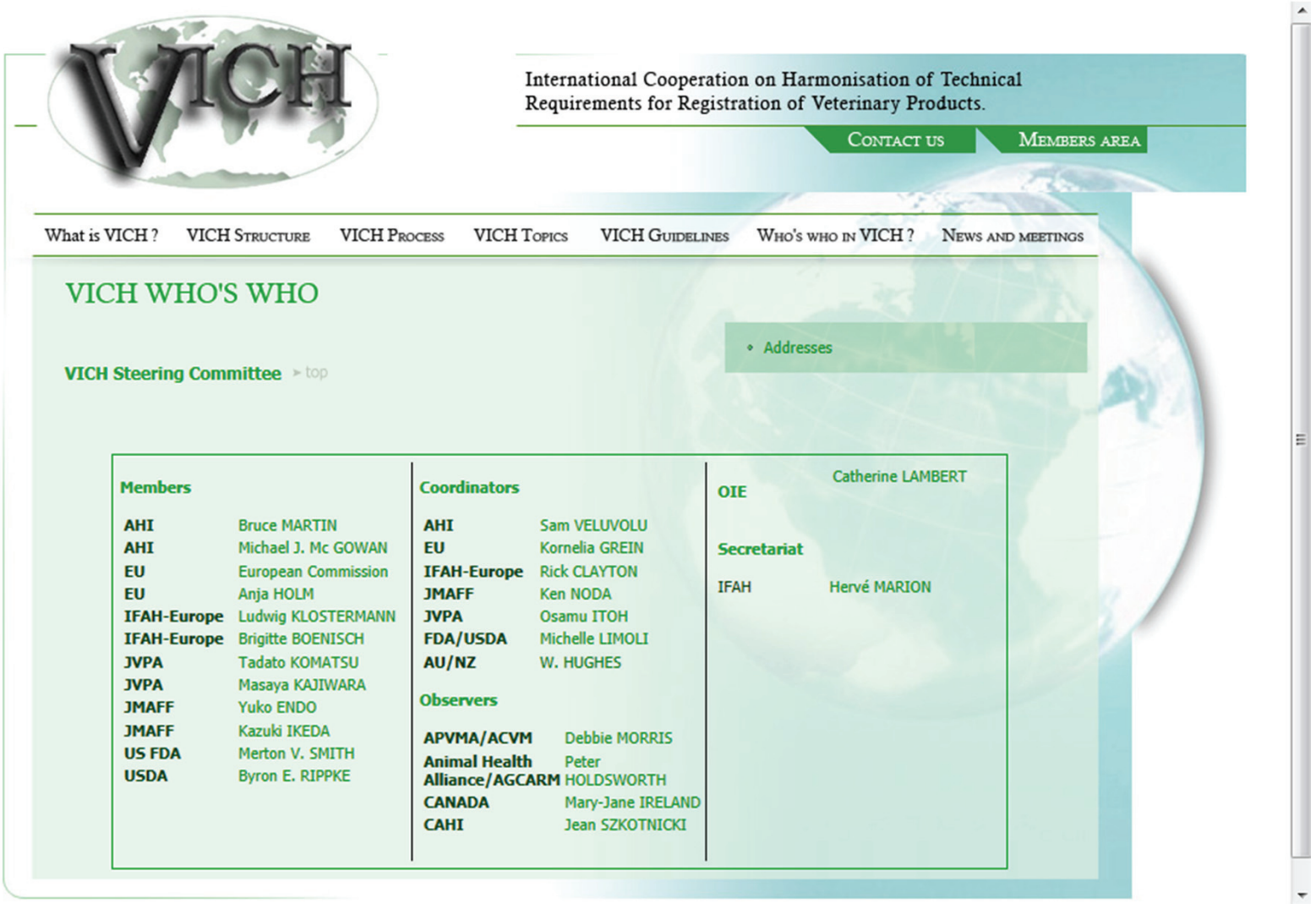
- Summary Table of VICH guidelines
- Official texts of final guidelines
- Official texts of draft guidelines
- VICH Guidelines by Category
- Documents in consultation

Re	Topic	TITLE OF GUIDELINES	In charge	Step Status	Step2	Step3	Step5	Step6	Impl. date
GL1	Validation definitions	Validation of analytical procedures: definition and terminology	Quality	Step 7	Mar. 97	Aug.97	Oct. 98	Oct. 98	Oct. 99
GL2	Validation methodology	Validation of analytical procedures : methodology	Quality	Step 7	Mar. 97	Aug.97	Oct. 98	Oct. 98	Oct. 99
GL3	Stability 1	Stability testing of new drug substances and products	Quality	Step 9	Sep. 97	Feb. 98	Mar. 99	May 99	May 00
GL4	Stability 2	Stability testing for new dosage forms	Quality	Step 7	Sep. 97	Feb. 98	Mar. 99	May 99	May 00
GL5	Stability 3	Stability testing : photostability testing of new drug substances and products	Quality	Step 7	Sep. 97	Feb. 98	Mar. 99	May 99	May 00
GL6	Ecotox Phase I	Environmental impact assessments (EIAs) for veterinary medicinal product (VMPs) Phase 1	Ecotoxicity	Step 7	Sep. 98	Oct. 98	Nov. 99	June 00	- Jul. 01
GL7	Anthelmintics	Efficacy of anthelmintics: general	Anthelmintics	Step 7	Aug. 98	Oct. 98	Nov. 99	Nov. 99	Dec.00

The VICH website

VICH Structure and organisation

The VICH website



Conclusions

- Much has been achieved over 15 years of activity, but much lies still ahead
- Consensus and mutual understanding are the keys to the success of VICH's development
- The Experts are the pillars of the VICH work
- VICH has the potential to eliminate duplications, to reduce timelines and to ensure a more efficient usage of available human material and animal resources, whilst safeguarding the quality, safety and efficiency of products
- The Wider International Harmonisation will enable to extend international harmonisation of regulatory requirements to further countries/regions

VICH PUBLIC WEBSITE

Final and draft Guidelines available on:

http://www.vichsec.org