



VICH

History, Functioning and Achievements

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VICH Secretariat

*VICH/OIE contact meeting on Wider International Harmonisation of
VICH Guidelines
Tokyo, November 15, 2011*



What is VICH?



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

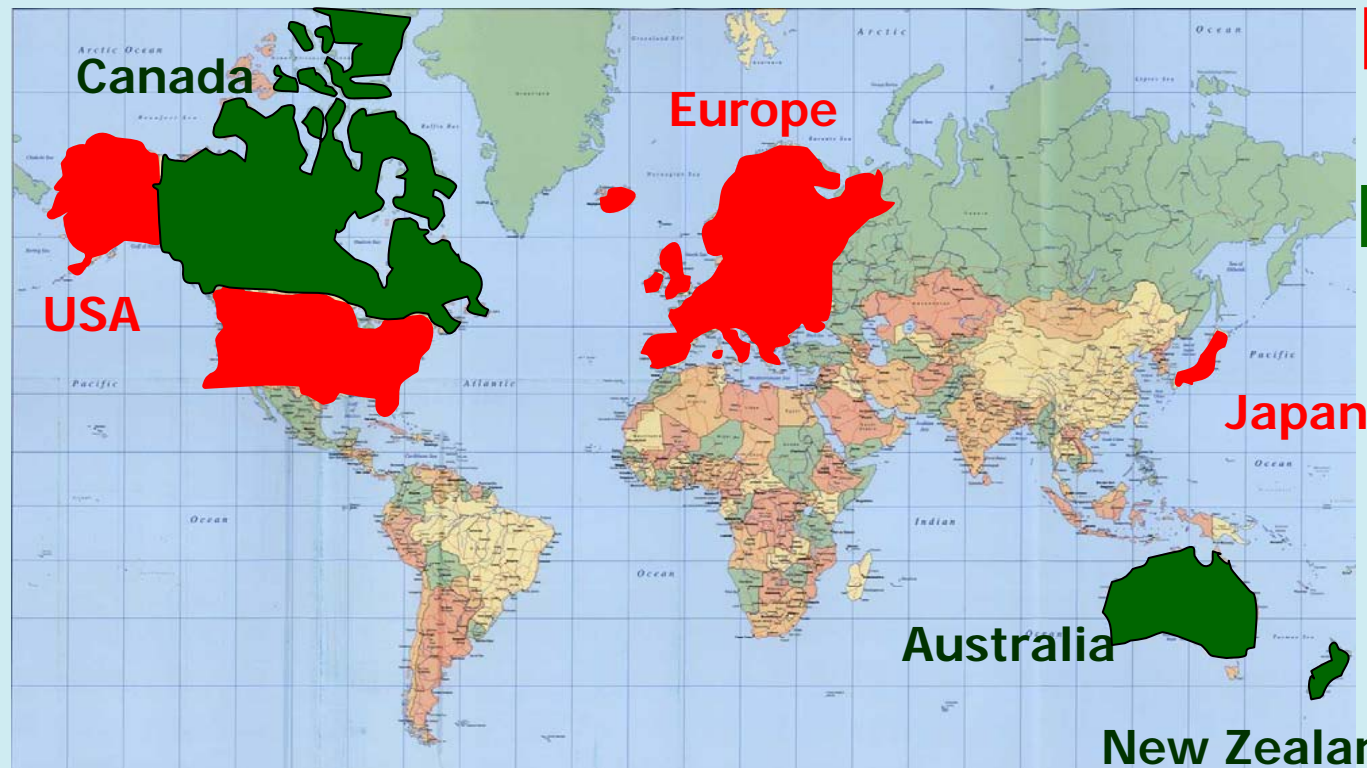
- International tripartite cooperation programme
- Brings together Regulatory Authorities and Industry



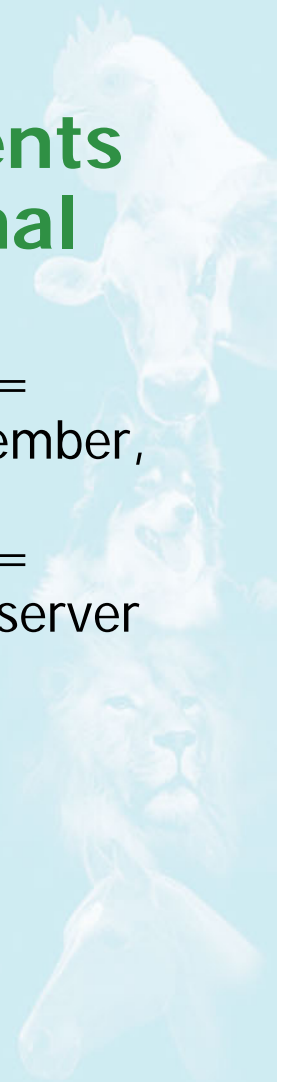
The VICH Regions



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



 =
VICH member,
 =
VICH observer



Developing VICH



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

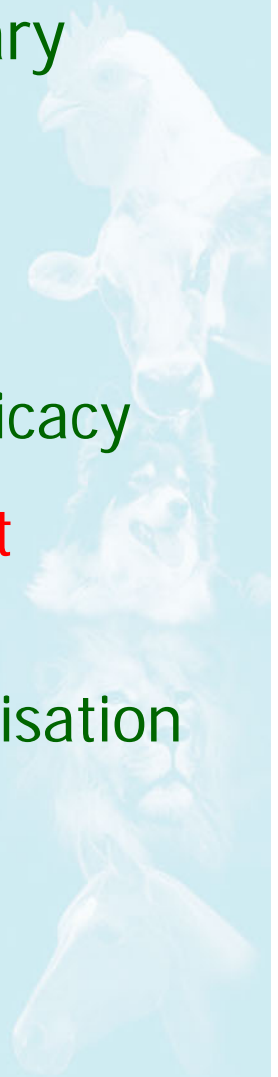


VICH Objectives



- 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 widening international harmonisation of registration requirements

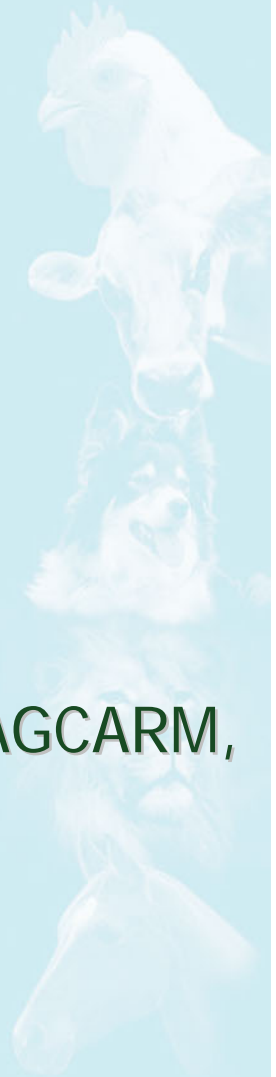
⇒ **VICH Outreach**



Members of the 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

Role of VICH/OIE/Codex



- **OIE** also is responsible for improving the legal framework and resources of national Veterinary Services
- The **Codex Alimentarius Commission** develops, on international level, food safety standards, guidelines and related texts such as
 - codes of practice under the Joint FAO/WHO Food Standards Programme to protect consumers and ensure fair practices in the food trade
 - maximum residue limits (MRLs) for residues from veterinary drugs in foodstuffs from animal origin under the Joint FAO/WHO Expert Committee of Food Additives (JECFA)
 - ⇒ Codex food safety standards

The VICH Process

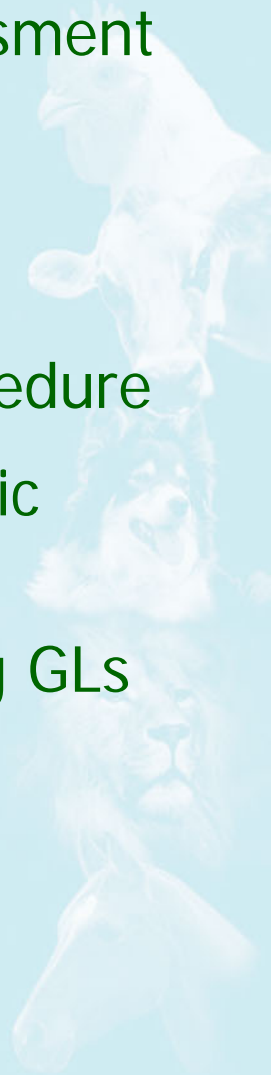


- The **VICH Steering Committee** drives the process: selects topics, releases draft guidelines for consultation, and adopts final guidelines for implementation
- **VICH Expert Working Groups** bring together the specific expertise for guideline development
- **Transparent guideline development** through 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 SC based on assessment of benefit to human and animal health through greater harmonisation, and resources management
- Work mandated by SC to Expert Working Groups
- Elaboration and adoption of guidelines in a 9-step procedure
- Follows closely ICH, taking account of veterinary specific needs
- Consequent need for maintaining and updating existing GLs on a regular basis



The VICH Process



VICH Steering Committee



Expert Working Groups

Quality EWG

Bioequivalence EWG

Safety EWG

Biologicals EWG

MRK* EWG

Microbiological ADI EWG

ESI⁺ EWG

* Metabolism and Residue kinetics

⁺ Electronic Standards Implementation

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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



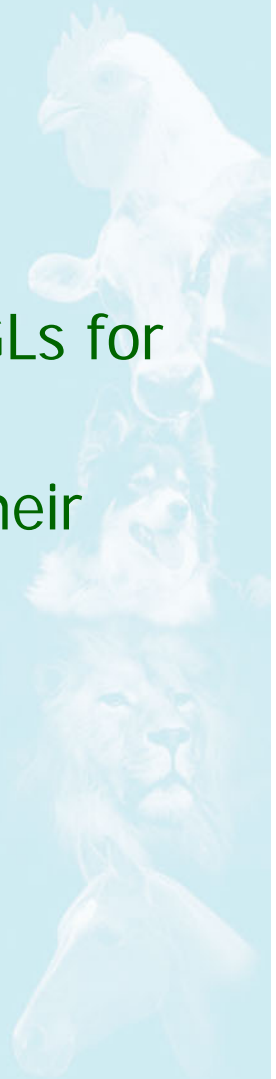
9 step procedure



The VICH Process



- Programme runs in cost-effective & transparent way
 - 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**
- ✓ Meetings are run in English (simultaneous translation can be organised at own cost - Japan)
- ✓ All documents (drafts and final) are written in English only
- ✓ VICH members may nevertheless translate the documents in their national language at their own cost

The VICH Process



- The Steering Committee meets regularly,
 - ✓ In principle every 8 to 9 months
 - ✓ 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 the implementation of the Guidelines in the regions
 - ✓ The working language is English
- The Expert Working Groups also meet regularly to progress their topics

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 between the participants!

- Considerable improvements of harmonization of data requirements between regions, thus
 - ✓ Reduction of animal testing
 - ✓ Reduction of costs
- Better understanding of regulations and concerns in the other regions
- Unique **discussion forum** between acknowledged worldwide scientific experts from both the Regulatory agencies and the Animal Health Companies



Achievements [2]



- **All decisions in the SC and the EWGs are made 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)
 - ➔ 8 new VICH Guidelines under development



Achievements [4]

- 47 finalised guidelines (GLs):
 - Implemented: 42
 - For implementation in 2012: 5
- New GLs under consultation/discussion: 8
- Revised GLs at step 9
 - Implemented: 6
 - Under review : 1
- Detailed list of GLs will be provided



Achievements [5]

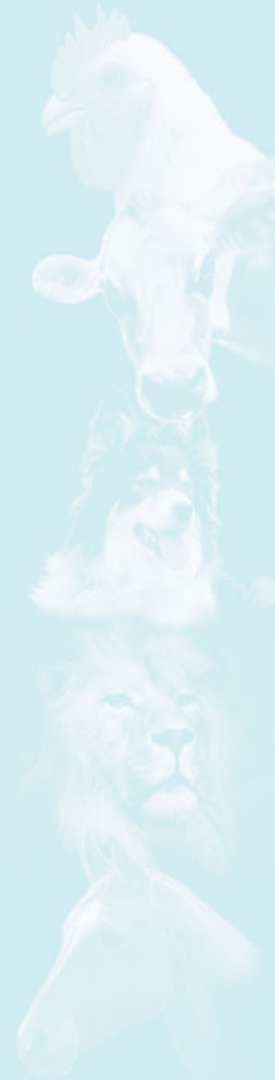


New GLs under discussion:

- 3 Pharmacovigilance GLs
- 3 Biological GLs
- 1 Safety GL
- 1 Bioequivalence GL

Final GL under Revision:

- 1 Quality GL



The VICH website



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

[CONTACT US](#)

[MEMBERS AREA](#)

- VICH 4 Conference**
(June 24 & 25, 2010 in Paris)
- *IFAH press release: VICH reaches out to non-VICH regions*
 - *VICH EWG Posters (in pdf)*
 - *Presentations*
 - *Pictures of the conference*

WHAT IS VICH ?

VICH is a trilateral (EU-Japan-USA) programme aimed at harmonising technical requirements for veterinary product registration. Its full title is the **International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products**. VICH was officially launched in April 1996.

[► Read More](#)



NEW VICH Leaflet NEW

"Harmonising the global processes for authorising veterinary medicines"

VICH AND ITS ROLE FOR AUTHORISATION OF VETERINARY MEDICINAL PRODUCTS (available in English-French-Spanish-Arabic & Chinese)

VICH GLOBAL OUTREACH STRATEGY - CURRENT THINKING OF THE STEERING COMMITTEE (available in English-French-Spanish-Arabic & Chinese)

VICH STRUCTURE

VICH PROCESS

VICH TOPICS

VICH GUIDELINES

■ [Overview of VICH structure](#)

■ [The Driver : The Steering](#)

■ [Quality](#)

■ [Summary table of VICH guidelines](#)

The VICH website



http://www.vichsec.org/en/guidelines4.htm

CEESA - European Animal Heal... Internet Explorer cannot displa... VICH - Guidelines

Google Rechercher Orthographe Saisie automatique Autres Connexion

VICH

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

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What is VICH? VICH STRUCTURE VICH PROCESS VICH TOPICS VICH GUIDELINES Who's who in VICH? NEWS AND MEETINGS

VICH GUIDELINES

Documents in consultation

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

Residual Solvents in new Veterinary Medicinal Products, Active Substances and Excipients (Revision at step 9)
Draft revised VICH GL18 (Quality-Impurities) - Released at step 4 for a 6-month public consultation period until October 31, 2010

Electronic Standards for Transfer of Data
VICH GL35 (Pharmacovigilance) - Released at step 4 for a 6-month public consultation period until March 15, 2011

Studies to evaluate the safety of residues of veterinary drugs in human food: general approach to establish a microbiological ADI
VICH GL36(R) (Safety) - February 2011 - Released at step 4 for a 6-month public consultation period until August 31, 2011

100%

The VICH website



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VICH GUIDELINES

Summary Table of VICH guidelines

- Summary Table of VICH guidelines
- Official texts of final guidelines
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- 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	1 - Jul. 01

100%

The VICH website



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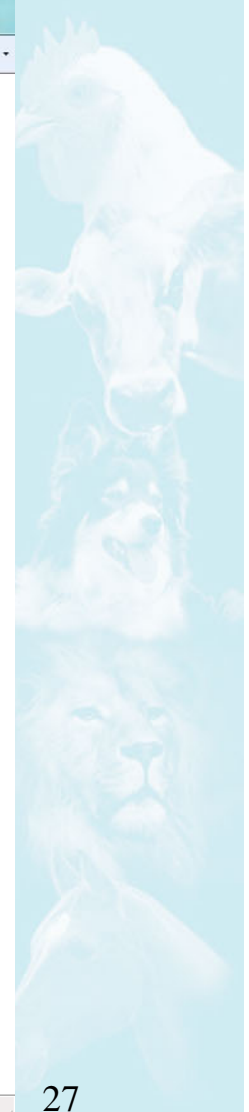
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VICH WHO'S WHO

[Addresses](#)

[VICH Steering Committee](#) > top

Members	Coordinators	OIE
AHI Bruce MARTIN	AHI Sam VELLUVOLU	Catherine LAMBERT
AHI Michael J. Mc GOWAN	EU Kornelia GREIN	Secretariat
EU European Commission	IFAH-Europe Rick CLAYTON	IFAH Hervé MARION
EU Anja HOLM	JMAFF Ken NODA	
IFAH-Europe Ludwig KLOSTERMANN	JVPA Osamu ITOH	
IFAH-Europe Brigitte BOENISCH	FDA/USDA Michelle LIMOLI	
JVPA Tadato KOMATSU	AU/NZ W. HUGHES	
JVPA Masaya KAJIWARA	Observers	
JMAFF Yuko ENDO	APVMA/ACVM Debbie MORRIS	
JMAFF Kazuki IKEDA	Animal Health Peter	
US FDA Merton V. SMITH	Alliance/AGCARM HOLDSWORTH	
USDA Byron E. RIPPKÉ	CANADA Mary-Jane IRELAND	
	CAHI Jean SZKOTNICKI	



Conclusions



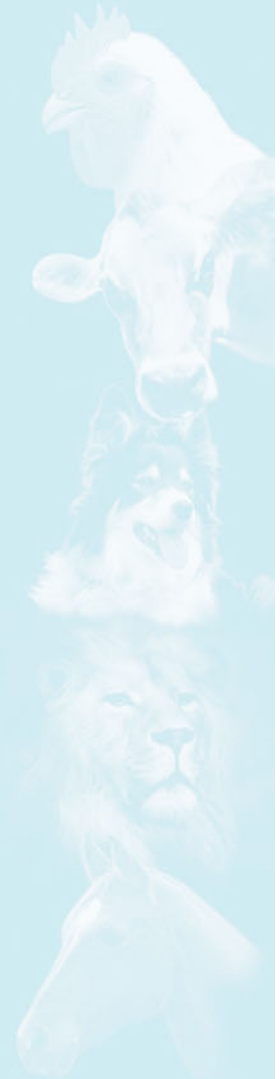
- Much has been achieved over 15 years of activity, but much lies still ahead
- Consensus and mutual understanding are the keys to the success of VICH's development
- The Experts are the pillars of the VICH work
- VICH has the potential to eliminate duplications, to reduce timelines and to ensure a more 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>





**THANK YOU FOR YOUR
ATTENTION !**

DO YOU HAVE ANY QUESTIONS?

