History, Achievements and Future

What is VICH ?

Paris, June 2010

History

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
April 1996	1st VICH Steering Committee in the OIE Offices in Paris
Nov. 1999	1st VICH Public Conference in Brussels (Europe)
Oct. 2002	2nd VICH Public Conference and 11th Steering Committee (Japan)
Oct. 2004	Adoption of the VICH Strategy for 2006-2010
May 2005	3rd VICH Public Conference and 16th Steering Committee (USA)
June 2008	First reflection on Global Outreach
June 2010	4th VICH Public Conference , 24th Steering Committee (Paris)

Benefits

- 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 scientific experts from both the regulatory agencies and industry
- Unique opportunity for regulators and industry to discuss topics openly enabling a pooling of expertise to jointly draft guidelines on regulatory data requirements.

Achievements

- 40 finalised GLs:
  - ✓ Implemented: 37
  - ✓ For implementation in 2010 & 2011: 3
- Revised GLs at step 9:
  - ✓ Implemented: 5
  - ✓ Under review: 2
- 13 Quality GLs:
  - ✓ Validation – Analytical methods (2)
  - ✓ Stability testing (5)
  - ✓ Impurities (3)
  - ✓ Specifications (2)
  - ✓ Bracketing and Matrixing (1)
- 8 Safety GLs ➔ Basic Toxic package
- 9 Efficacy of Anthelmintics GLs ➔ All animal species
- 2 Ecotoxicity GLs ➔ Environment
- 3 Target Animal Safety
- 2 Biologicals testing GLs ➔ Harmonised global approach
- 1 Pharmacovigilance GL ➔ PSURs
- 1 GCP GL
- 1 Antimicrobial Resistance GL

18th VICH Steering Committee – London, May 2006

Current activities

New GLs under discussion:

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

Final GLs under Revision:

- 1 Quality GL
- 1 Microbiological ADI (Safety) GL

Future – VICH Phase III

- Evaluate new concept papers for new topics
- Develop new VICH guidelines where feasible
- Monitor and maintain existing VICH guidelines
  - ✓ Check need to review existing GLs every 3 years
  - ✓ Monitor the consistent implementation in the regions
- The outreach of VICH Guidelines to non-VICH countries
- Improve communication and consultation with relevant organisations outside the VICH regions

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