History, Achievements and Future

**History**

- 1991: Creation of ICH with 1st conference
- 1992: 7th ITCDVR conference in Argentina: concept of VICH
- 1994: OIE ad hoc group: scope, membership and objectives of VICH
- April 1999: 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 15th Steering Committee (USA)
- June 2008: First reflection on Global Outreach
- June 2010: 4th VICH Public Conference, 24th Steering Committee (Paris)

**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 Matixing (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

**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.

**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

**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

**18th VICH Steering Committee - London, May 2006**