VICH and the Registration of Veterinary Drugs

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CVM Organizational Chart

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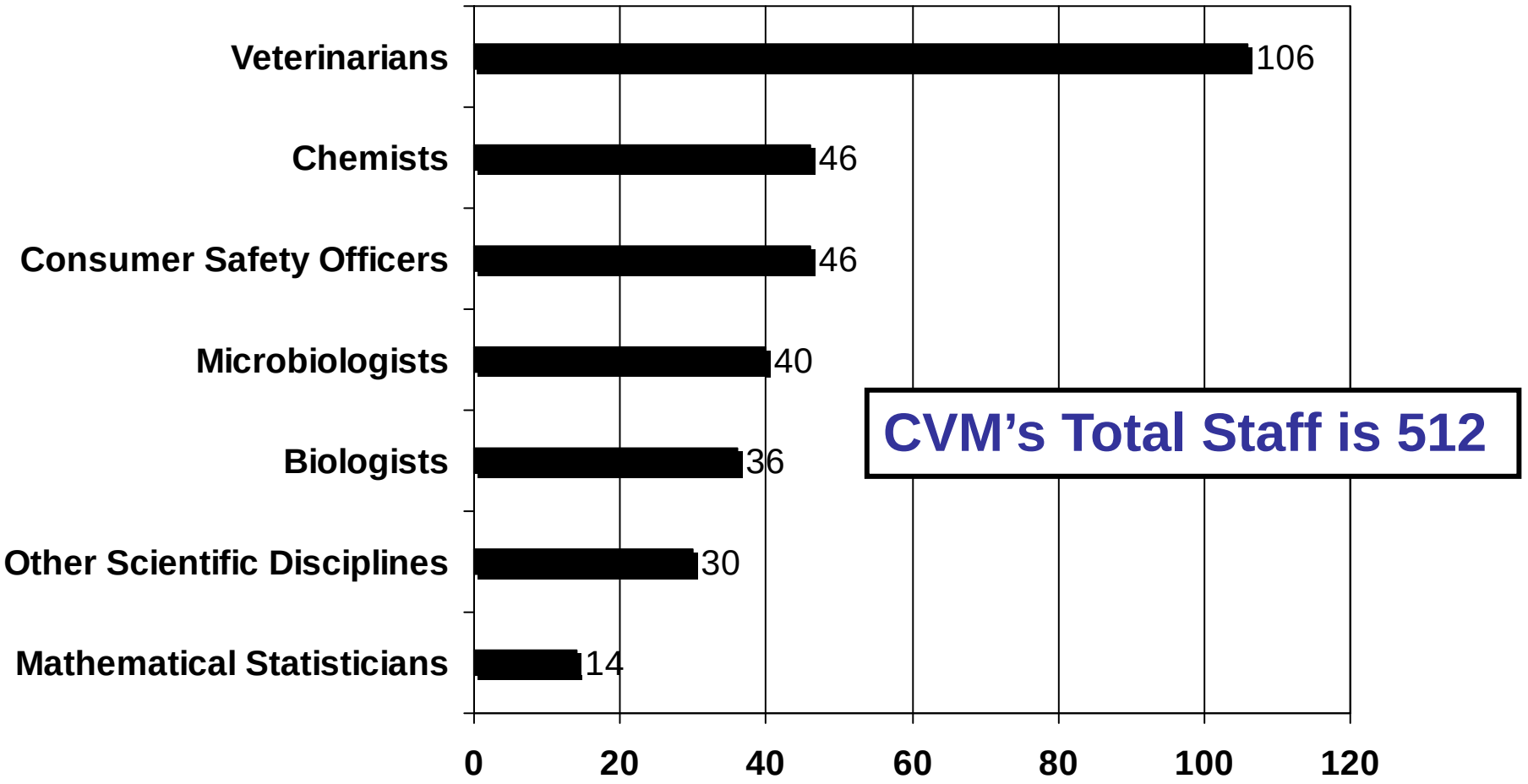
Scientific & Technical Disciplines at CVM



CVM's Total Staff is 512

CVM International Activities

- International Cooperation on Harmonization of Technical Requirements for the Registration of Veterinary Medicinal Products (VICH)
- Support OIE programs to help strengthen national veterinary drug regulatory infrastructures to ensure the availability of safe and effective products to mitigate animal disease, including zoonoses

- **VICH** = International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products
- An international program of cooperation and information exchange
  - with goal of reaching consensus on data requirements and study protocols needed to show safety, quality, and efficacy for registration or licensing veterinary medicinal products

Regulatory Infrastructure

- FDA, OIE support building stronger veterinary medicine regulatory infrastructures
- Regulators around world use nearly universal model
  - based on veterinary legislation and regulation
  - requires demonstration of quality, safety, efficacy, with post-market surveillance, controls
- VICH goal – provide science-based tools to regulators in many countries
  - that address public and animal health

VICH Goals

- Draft guidelines for pre-market studies
  - to ensure high product standards – quality, safety, efficacy
  - protecting public and animal health, animal welfare, the environment
  - minimize use of test animals, reduce costs of product development
  - Regulators, industry, human and animal protection groups generally support

VICH Goals

- Implement harmonized regulatory requirements for animal drugs in VICH countries/regions
- Facilitate, accelerate product authorization
- Provide basis for future international harmonization of registration requirements
- Provide forum for dealing with new, emerging global issues, relevant science

VICH Participants

- Regulatory Agencies
  - **USA** = FDA and USDA's APHIS
  - **EU** = EMA (and European Commission)
  - **Japan** = MAFF (and NVAL, MHLW and FSC)
  - **Australia/New Zealand** = APVMA and NZFSA
  - **Canada** = VDD

VICH Participants

- Industry representatives
  - **USA** = AHI
  - **EU** = IFAH Europe
  - **Japan** = JVPA
  - **Australia/New Zealand** = AHA/AGCARM
  - **Canada** = CAHI
- Other participants
  - IFAH Global
  - OIE

The VICH Process

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	• Official consultation in three 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 repeated

VICH – What It Does And What It Does Not Do

VICH does:

- harmonize test requirements for the authorization of veterinary medicines
- ensure that test requirements are based on the current state of science
- reduce need to repeat studies
  - full VICH partners commit to accepting studies performed to VICH GLs, observers voluntarily accept
- support animal welfare by wider study acceptance and reducing need for test animals

VICH does not:

- provide a legislative structure for regulatory system for veterinary medicines
- harmonize the interpretation of test results
- guarantee authorization, even if all tests are done in accordance with VICH guidelines
- harmonize all areas of testing veterinary medicines
  - only where there is an agreed need of regulators and industry of VICH regions and observers

Development of Guidelines

- Finalized and implemented guidelines: **More than 40**
  - already revised: **6**
  - currently under revision: **3**
- Several guidelines out for comment, or out for comment soon, and expected to be implemented during the next 2 years
- Other guidelines under early development or under consideration
- More information: http://www.vichsec.org/

VICH Outreach

- VICH determining participation of additional countries, regions
- VICH wants to communicate role, benefits of harmonization
- OIE supports VICH outreach

Why Participate?

- Collective voices at November meeting likely to change VICH process
- Through your participation, you can gain better understanding of science behind guidelines
- Could facilitate adoption of guidelines in more countries
  - which could lead to more registrations, better protection of human and animal health

Why Participate?

- VICH global goals offer unique opportunity
  - for industry to work with regulators to exchange information
- Uses a transparent process
  - for development of harmonized, science-based standards for public, animal health protection
- VICH work leads to certainty, predictability in regulatory process
- Helps make more products available

Thank You

Keep Up to Date

www.fda.gov/Animal&Veterinary

Reference the CVM Website for the most current information