“An industry perspective on putting global animal welfare principles into action”

Sherry Vaughn DVM
Global Animal Welfare Compliance
Zoetis Research and Development
Kalamazoo, Michigan
USA
Agenda for today’s presentation

1. My background and One Health
2. About Zoetis and its mission in the animal health industry
3. Creating a corporate culture of global animal welfare
4. Animal welfare standards in a global environment
5. Expectations of today’s animal scientists
6. Q & A
7. Resources
My Background

BS; New Mexico State University
DVM; Colorado State University

Veterinary Practice and Research
• Many species including NHPs
• Simian Hemorrhagic fever/Ebola

Currently Zoetis VMRD, Kalamazoo, Michigan

Interests: Public Health, Infectious disease research, research ethics and welfare for animals and people
One Health

“Approximately 60% of all human pathogens are zoonotic and 75% of recent and emerging diseases affecting humans are diseases of animal origin” (CDC)

One Health: Global optimal health for people, animals and the environment: It’s all connected!

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Our History and Heritage

- Pfizer researchers discovered Terramycin, marking our entry into animal health
- Launched Liquamycin LA 200
- Acquired SmithKline Beecham’s animal health division
- Launched Draxxin, Convenia, Cerenia, Palladia and Improvest
- Acquired Pharmacia Corporation and CSL Animal Health
- Established dedicated R&D headquarters in Kalamazoo, Mich.
- Established vaccine manufacturing capabilities in China
- Pfizer announced that its Animal Health business will become a standalone company called Zoetis
- Pfizer sold minority stake in Zoetis. Zoetis became a standalone company.
- Launched Apoquel


- Animal Agriculture division formed; renamed Pfizer Animal Health in 1988
- Launched Dectomax, Rimadyl, Clavamox and Revolution
- Pfizer announced that its Animal Health business will become a standalone company called Zoetis
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Note: 2013 facts and figures shown
Zoetis Global VMRD Network

* Co-located with a manufacturing operation
Leadership in Product VMRD

Zoetis Veterinary Medicine Research & Development (VMRD) is committed to continuously innovating to develop animal health solutions that meet the needs of those who raise and care for animals.

We apply our research to a broad and diverse range of species, therapeutic areas and geographic regions.

Our areas of focus are:

• Vaccines
• Medicines
• Genetics
• Diagnostics
Kalamazoo Headquarter Facilities

Downtown \[7 \text{ miles} / 11 \text{ km}\] Richland Farms

- Global Biologics Research
- Global Therapeutics Research
- Global Development & Operations
- Global Laboratory Sciences
- Global Regulatory Affairs
- Research Strategy & Portfolio Management
- Animal Research Support
- Genetics Research
- Diversified Research Operations

- Containment facilities
- Parasite ‘colony’
- Microbiology
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Creating a Corporate Culture of Global Animal Welfare

• Zoetis became a standalone company in 2013

• What actions did we need to take as a new global company to create a culture that would entwine Animal Health, Animal Welfare and our Core Ethical Belief of “Always Do the Right Thing?”

“Integrity is the guiding principal for all our decisions and relationships. We are honest and trustworthy in our words and actions.”
Creating a Corporate Culture of Global Animal Welfare: Action Plans

• Internal conversations on importance of animal research and testing and importance of high humane standards:
  – Privilege to use animals in research and testing
  – Ethical contract with society, our shareholders and our employees most importantly - the animals

• Development of a Corporate Policy on animal use

• Creation of Global Animal Welfare Teams
Animal Research

- Essential to the success of the Zoetis Mission

- Given present state of knowledge, testing potential new medicines and therapies in animals is critical to regulatory authorities worldwide
Caring for animals - in research and in the field (Corporate Policy)

• Zoetis is **ethically and legally obliged** to rigorously evaluate new medicines and therapies.

• Given the present state of scientific knowledge, testing these potential new medicines and therapies in animals is frequently **critical to this evaluation**.

• **Required by regulatory authorities** worldwide to ensure the quality, efficacy and safety of the medicines we discover.

• Zoetis accepts its responsibility for conducting animal research in an **humane and ethical** manner and expects all employees to treat animals with respect.

• Every proposed use of animals in our research is **thoroughly evaluated** before being undertaken and **the health and well-being of all animals under our care is a primary concern**.

• We expect any **third party research organization** we engage to conduct animal based research on our behalf to adhere to our Policy and to comply with all applicable laws and regulations.
How do we ensure high standards are met?

Accreditation by the Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC), an independent, non-profit, peer-review organization reflects our absolute commitment that animals used in research and testing are treated humanely and helps mitigate worldwide variation in animal care.
Zoetis Animal Welfare Teams

Animal Welfare Board
Animal Care and Ethics Council
Accreditation Readiness Team
Third Party Risk Assessment Team
Ethics Committees, Veterinarians, Animal Care, and Scientists
Global Animal Welfare Board Responsibility

• Governs animal welfare and sets standards
• Drives execution of corporate policy on animal care and use internally and externally
• Communicates and educates on policies
Global Animal Care and Ethics Council
Responsibility

- Executes the Animal Welfare Board policies
- Drives harmonization
- Education and mentoring
- Open forum for discussion of animal welfare issues
- 25 members
- Meet monthly
Global Third Party Risk Assessment Team Responsibility

- Mitigates risk of using third party sites for research,
- Conducts animal welfare audits and followup
- Influences how our high standards will be met by communication, education, and mentoring third parties on expected standards
- 14 members
- Meet weekly
Global Accreditation Readiness Team

Responsibility:

• Assists Zoetis sites maintain AAALAC accreditation, which are the expected high standards
• Helps new sites become accredited
• Education, mentoring, and harmonization
• 16 members
• Meet monthly
Institutional Animal Care and Use Committees, Ethics Committees, Veterinary, Animal Care Staff and Scientist Responsibility:

• Local compliance with Corporate Policies, regulations and working to maintain high standards of animal welfare
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Animal welfare standards in a global environment

• What factors influence global animal welfare?
• What standards do we use?
• What are the 3Rs and how do we progress them?
• China case study
What might influence variations in animal care worldwide?

Variation may be driven by differences in:
- Economic development of the country
- Resources committed to science (national priority)
- Philosophical, religious, and cultural context of animal use
- Communication differences-availability of information through the Internet or information published in relevant language
- Different regulatory frameworks from none to simple to complex
- Difference in the manner in which animal welfare regulations are enforced
What might influence variations in animal care worldwide?

Strength of Processes in place:

- Rigor of ethical review process
- Quality and frequency of animal facility inspections,
- Quality of Program and SOP review
- Method of dealing with animal welfare concerns

Veterinary qualifications and training variations internationally
Availability of animal welfare training to ensure proficiency
What standards are used?
Zoetis policies, international standards, country standards

Corporate Policies:

- Corporate Policy (“high standards”)
- Guide for the Care & Use of Laboratory Animals-8th edition
- Guide for the Care and Use of Agriculture Animals-3rd edition (FASS)
- International: OIE: Terrestrial animal health code

National Legislation and Standards (Europe):

- EU Directive 2010/63/EU on Protection of animals for Scientific Purposes
- ETS 123-European Convention on for the Protection of Vertebrate animals used for Experimental and other Scientific Purposes
OIE World Organization for Animal Health: Terrestrial AH code, Chapters 7,8
Use of Animals in Research and Education

• Main topics
  – 3 Rs
  – Oversight framework
    • Project review
    • Harm/benefit analysis
    • Facility inspections
    • Ethical evaluation (policies/practices of institution)
  – Assurance of training and competency
  – Provision of Veterinary care
  – Source of animals
  – Physical facility and environmental conditions
  – Husbandry
  – Transportation

• Adopted by 178 member countries and territories
  • http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_1.7.8.htm
What are the 3Rs?

Internationally accepted ethical framework for conducting animal experiments using animals humanely

First introduced in Russell and Burch’s 1959 book “Principles of humane experimental technique”

- **Reduction**: methods which reduce the animal numbers
- **Refinement**: methods which improve animal welfare
- **Replacement**: use of non-animal methods
How do we progress the 3Rs?

The Zoetis Global Animal Welfare Board conducts a 3R’s Award Program that reflects the core commitment to promoting, understanding, and implementing alternatives and rewarding scientific creativity.

Examples:

• Rabbit social housing development
• Adoption program development
• Using retrospective data to support marketing messages rather than run additional studies
• Removal of the need for Target Animal Batch Safety Test (TABST) for batch release purpose for most Zoetis vaccines in the EU
How do we progress the 3Rs?

In addition, Zoetis participates in cross-industry efforts with organizations that promote the 3Rs, such as:

- The European Partnership for Alternatives to Animal Testing (EPAA): voluntary collaboration between the EU commission, trade associations, and companies from 7 industry sectors, committed to accelerating the development, validation, and acceptance of 3R approaches. [http://ec.europa.eu/enterprise/epaa/index_en.htm](http://ec.europa.eu/enterprise/epaa/index_en.htm)

- National Center for the 3Rs (NC3Rs): advances new technologies and approaches to minimize use of animals and improve animal welfare, and stimulate changes in regulations and practice. [http://www.nc3rs.org.uk](http://www.nc3rs.org.uk)

- International Federation for Animal Health (IFAH): voice of the EU animal health industry, contributing to a high standard of welfare. [http://www.ifaheurope.org](http://www.ifaheurope.org)
3R opportunities in drug development

Discovery and Early development
Harmonization of regulatory requirements
Refinement opportunities in every study (animal comfort)
China case study: Approach to global animal welfare

Actions:

Review of Chinese regulations

- “Regulations for the administration of affairs concerning experimental animals”
- “Guidance of Caring Laboratory Animals” compared to the OIE guidance and the “Guides”
- Gained understanding of manner in which regulations are enforced
- Gained understanding of ethical review process
- Site visit performed using Chinese regulations, the OIE guidance, the “Guides” and Zoetis policy
China Case study: Approach to global animal welfare

**Actions:**

- Formation of a Zoetis led ethical review team
  - Evaluates animal care programs, SOPs, animal protocols
  - Conducts inspections, and reviews program
  - Investigates animal welfare concerns.

- Added enhanced veterinary oversight

- Knowledge sharing and mentorship
  - Continuing site visits
  - Continuing training
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What are your responsibilities as a scientist?

• Follow all regulations and policies regarding animal welfare. Reach for high standards to keep that contract with the animals and society.

• Trust your “gut instinct”-if it seems unethical, or you can see a more animal friendly method to achieve the research goal- bring it forward to the appropriate parties.

• Be Creative! Use your scientific knowledge to lead the way to develop \textit{in vitro} alternatives, refine methods, or reduce animal numbers.

• Ensure quality ethical review is in place- use biostatisticians to ensure animal numbers are appropriate. Seek out your veterinary consultants for input. Ensure the harm/benefit analysis is aligned with your personal ethic code.

• Influence other scientists and be a personal advocate for animal welfare!

KEEP LEARNING and ASKING QUESTIONS
QUESTIONS?
RESOURCES

http://www.aaalac.org/resources/internationalregs.cfm
http://www.ifahsec.org/
http://ec.europa.eu/enterprise/epaa/
  • http://www.nc3rs.org.uk/
  • http://www.avma.org/One-Health
  • http://CDCD
• Photo Credit: http://www.lotholotho.com/2012/03/something-great.html