



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

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# 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**

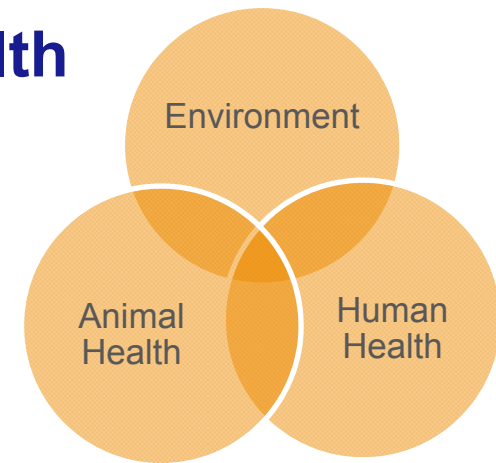


# One Health



“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!**

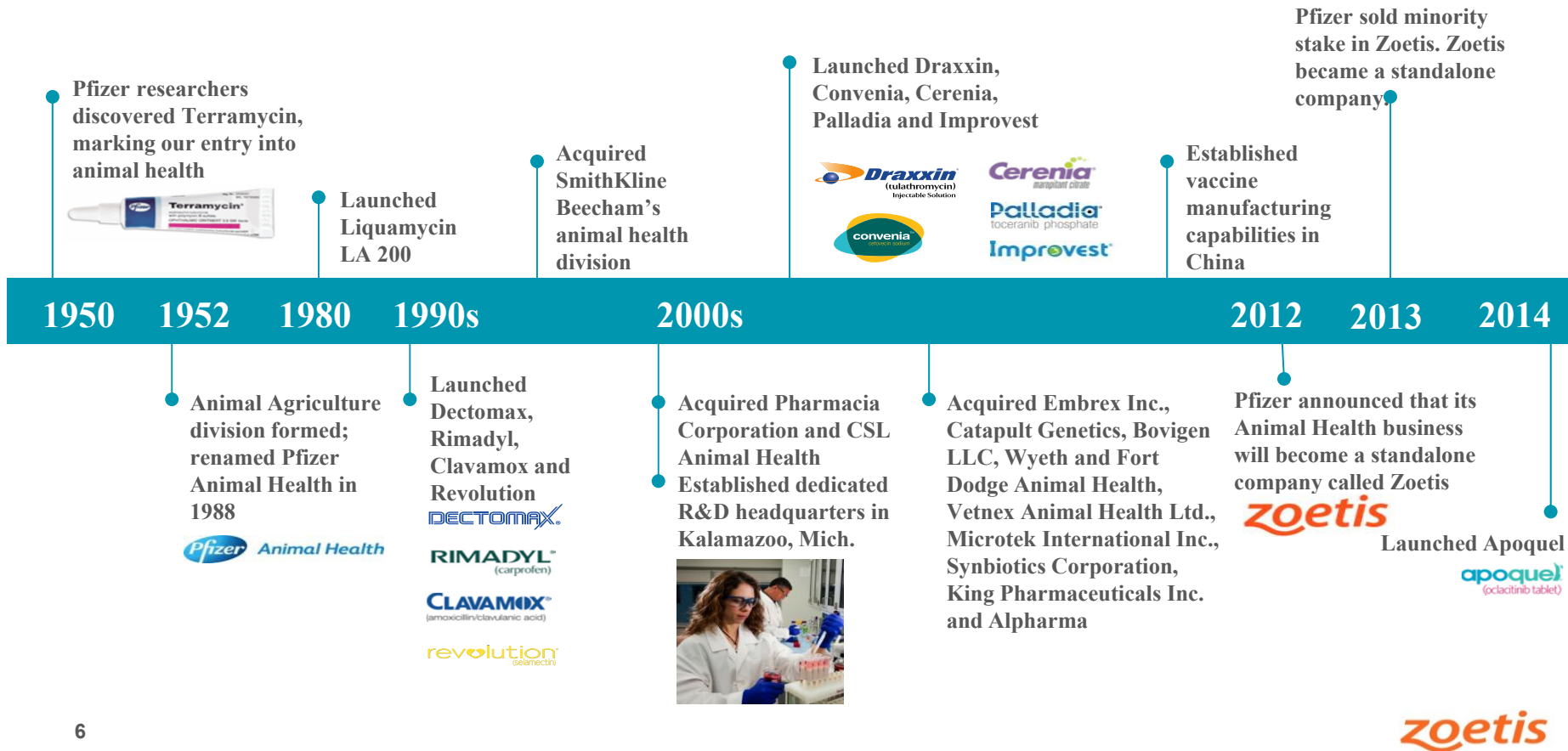


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# Our History and Heritage



**28** MANUFACTURING SITES

**8** CORE ANIMAL SPECIES



**\$4.6+**  
**BILLION**  
SALES



R&D EMPLOYEES

**1,100+**

**300+** PRODUCT LINES



**3,500+**  
MEMBER ZOETIS  
FIELD FORCE

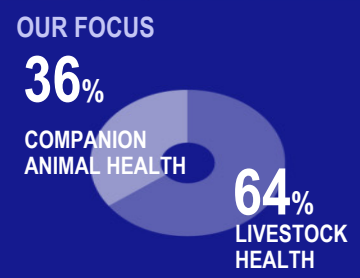


**60+** YEARS OF EXPERIENCE

**5** MAJOR PRODUCT CATEGORIES

MARKET PRESENCE IN  
**120+**  
COUNTRIES

COLLEAGUES AROUND THE WORLD  
**9,800+**



WE PROVIDE  
**MEDICINES**  
**VACCINES**  
**DIAGNOSTICS**  
**GENETICS**

7 Note: 2013 facts and figures shown



# Zoetis Global VMRD Network





# 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



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# Kalamazoo Headquarter Facilities

## Downtown



- 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

10

7 miles / 11 km

## Richland Farms



- 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  
Animal Care  
And Ethics  
Council**

# 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  
Third Party  
Risk  
Assessment  
Team**

# 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



**Global  
Accreditation  
Readiness  
Team**

# 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



**Local Ethics committees, Veterinarians animal care staff and scientists**

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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**

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# What standards are used?

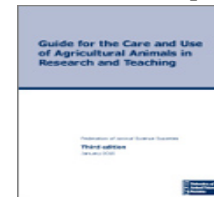
## Zoetis policies, international standards, country standards

### Corporate Policies:

- Corporate Policy (“high standards”)
- Guide for the Care & Use of Laboratory Animals-8<sup>th</sup> edition
- Guide for the Care and Use of Agriculture Animals-3<sup>rd</sup> 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

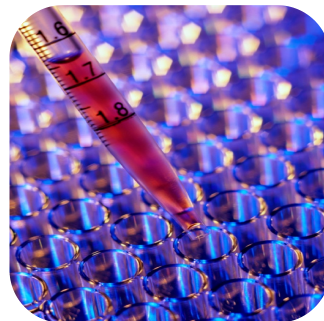
- Main topics
  - 3 Rs
  - Oversight framework
    - Project review
    - Harm/benefit analysis
    - Facility inspections
    - Ethical evaluation (policies/practices of institution)
  - Assurance of training and competency
  - Provision of Veterinary care
  - Source of animals
  - Physical facility 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](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.

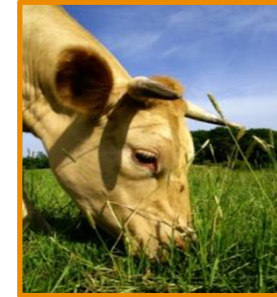
## Examples:

- 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.

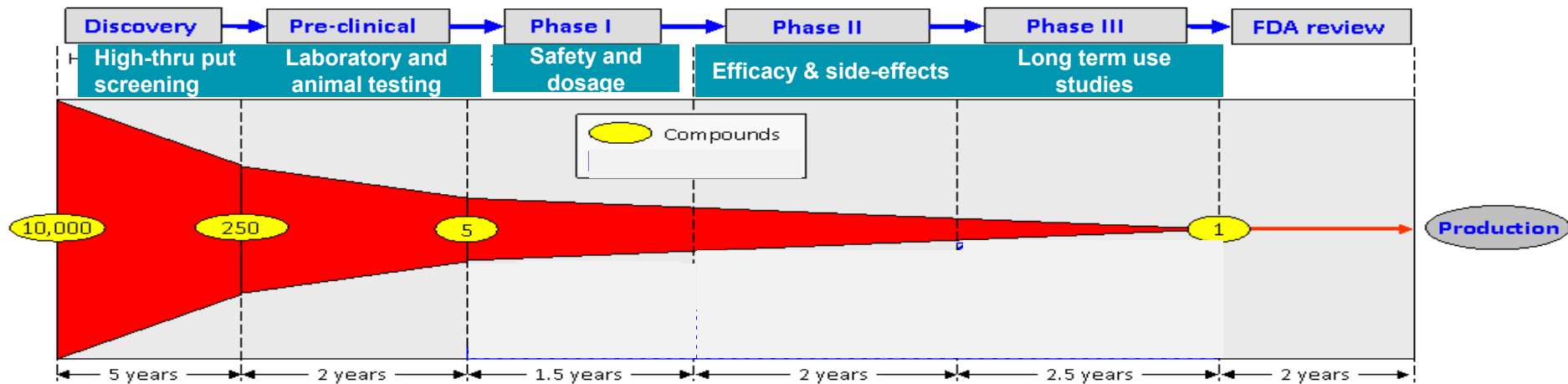
<http://www.nc3rs.org.uk>

- International Federation for Animal Health (IFAH): voice of the EU animal health industry, contributing to a high standard of welfare

<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 *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!

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>