



Batch Safety Test Exemptions

**Angela Walker, D.V.M., Ph.D.
Center for Veterinary Biologics
1920 Dayton Avenue
Ames, Iowa USA 50010**

Email: Angela.M.Walker@usda.gov

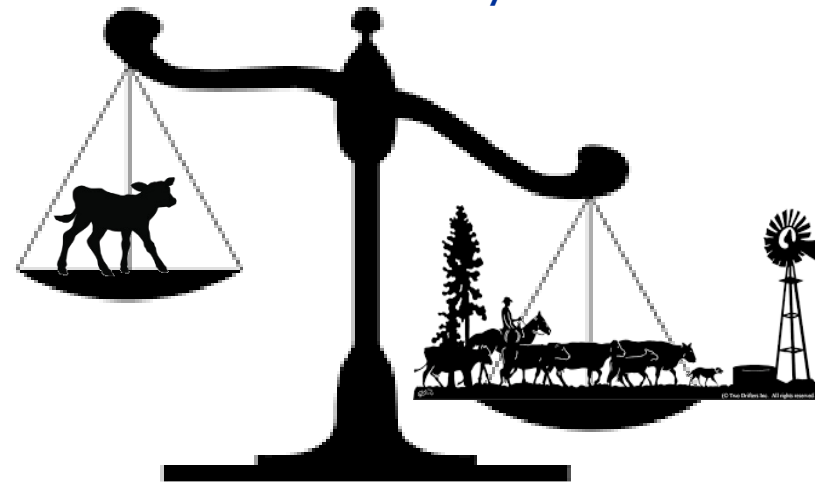
Batch Safety Tests

- Designed to keep end users safe
 - Target Animal Safety Tests
 - Laboratory Animal Safety Tests



VICH Guidance

- **VICH GL50:** Harmonisation of criteria to waive **target animal batch safety testing** for **inactivated** vaccines for veterinary use (Last updated June 2017)
- **VICH GL55:** Harmonisation of criteria to waive **target animal batch safety testing** for **live** vaccines for veterinary use (Last updated June 2017)
- **VICH GL59:** Harmonisation of criteria to waive **laboratory animal batch safety testing** for vaccines for veterinary use



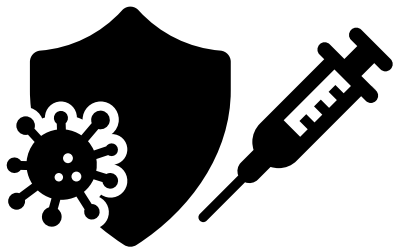
VICH Considerations

- Consistent, quality manufacturing processes as determined by a regulated authority
- Seed lot manufacturing system
- Sufficient number of batches pass previous batch safety testing
- Pharmacovigilance Data



VS Memorandum 800.116

- Target Animal Batch Safety Test Exemptions
 - Consistent, quality manufacturing processes
 - Report providing an assessment of all aspects of the product's safety performance
 - Seed lot manufacturing system
 - Sufficient number of batches pass previous batch safety testing
- Pharmacovigilance Data
 - Summaries of adverse events should be provided to the CVB annually per license restriction



Complications (Globally)

- Individual Country Needs
 - Is oversight based more heavily on GMP or final product testing?
 - Experiences of an individual country
- Pharmacovigilance Implementation
 - Work flow for gathering the data
 - Interpretation of the data gathered

