Batch Safety Test Exemptions

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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