Veterinary GCP Compliance Checklist

Trial Site Management

1. General Site Requirements

- Appropriate facilities for the species, including secure housing and treatment areas
- Clearly defined, clean, and appropriately equipped treatment, examination, and storage areas
- Secure areas for storage of investigational veterinary product (IVP)

2. Documentation and Recordkeeping

- Site Master File (SMF) including site layout, SOPs, equipment, personnel details
- Study protocol and all amendments signed and dated by Principal Investigator (PI)
- Signed and dated informed consent forms from animal owners (when applicable)
- Accurate and complete case report forms (CRFs), electronic data collection (eCRFs), and source documents
- Inventory records for investigational veterinary product receipt, dispensing, and return/destruction

3. Investigator and Personnel

- Qualified and trained Principal Investigator (PI) clearly identified
- Staff training records on GCP, protocol-specific procedures, and IVP handling
- Clearly defined roles and responsibilities documented for all personnel involved
- Documentation of delegation of duties and qualifications for each task

4. Ethics and Regulatory Compliance

- Valid approval by Ethics Committee (Institutional Animal Care and Use Committee (IACUC) in the US; Ethics Committee approval in the EU)
- Compliance with national/local regulatory authority guidelines (FDA CVM, EMA, national veterinary authorities)

- Regular updates to Ethics Committee regarding significant protocol amendments, adverse events, or safety concerns

5. Study Protocol Compliance

- Strict adherence to approved study protocol procedures and eligibility criteria
- Documented deviations with clear justification, reporting, and corrective actions
- Regular monitoring of protocol adherence (internal and external audits)

6. Animal Welfare Compliance

- Compliance with relevant animal welfare regulations (e.g., Animal Welfare Act, Directive 2010/63/EU)
- Adequate veterinary care provided throughout the study
- Regular welfare monitoring documented in detail

7. Investigational Veterinary Product (IVP) Management

- IVP securely stored, temperature monitored and recorded as required
- Accurate IVP accountability logs (including batch numbers, expiration, dispensing, and disposal)
- Clear labeling of IVP, avoiding confusion with other veterinary products

8. Adverse Event (AE) Reporting and Safety Monitoring

- Systematic capture and documentation of adverse events
- Prompt AE reporting to sponsor, FDA CVM, EMA, and relevant ethics committees as per regulations
- Defined timelines and procedures for managing and documenting serious adverse events (SAEs)

9. Quality Assurance and Auditing

- Site-specific quality assurance program, clearly documented in SOPs
- Routine internal audits and inspections with clear documentation and follow-up actions
- Readiness for external regulatory inspections (FDA, EMA)

10. Archiving and Data Retention

- Secure, controlled-access archive storage for study documentation
- Archiving period clearly defined (typically a minimum of 5 years after study completion or per national regulations)
- Documented procedures for document retrieval from archive as needed

11. Equipment and Calibration

- Maintenance and calibration records for all study-related equipment (scales, laboratory equipment, temperature monitoring, etc.)
- Documented SOPs for calibration, operation, and maintenance of equipment

12. Laboratory Compliance

- Accredited and validated laboratory methods
- Documented SOPs for sample handling, processing, analysis, and reporting
- Clearly documented sample tracking and chain-of-custody procedures