Animal Health Product Regulatory Services

Award-Winning Consultancy Providing Innovative Solutions to Meet Regulatory and Environmental Challenges

CSI provides data evaluation, exposure modelling and regulatory support to meet the requirements of animal health product legislation. CSI specialises in the preparation of EU Environmental Risk Assessments/US Environmental Assessments (ERA/EA) and EU User Risk Assessments (URA).

Support for Product Registration

Environmental and User Safety of animal health products in the European Union are regulated under Directive 2001/82/EC as amended. Animal health products used in the U.S. are potentially subject to Food and Drug Administration (FDA) environmental assessment requirements and, for certain product applications, the U.S. Environmental Protection Agency (EPA) or U.S. Department of Agriculture (USDA) may have jurisdiction.

Data Evaluation

Evaluation of existing data, data gap analysis and literature searching.

Study Monitoring / Data Development

Identification of required studies to support registration objectives. Placement and monitoring of tests at contract research organisations (CRO's), and review and interpretation of study results.

Environmental Fate and Ecotoxicology Data Review

Identification of relevant endpoints for fate and behaviour (metabolism and excretion, degradation and soil adsorption) and toxicity (soil organisms, aquatic organisms and dun fauna).

Environmental Risk Assessment

Conduct EU Environmental Risk Assessments and US Environmental Assessments (ERA/EA) Phases I and II according to Veterinary International Conference on Harmonization (VICH) Guidelines. Calculation and comparison of Predicted Environmental Concentrations (PECs) in surface water, groundwater, soil, sediment and dung with determined Predicted No Effect Concentrations (PNECs) to derive the risk quotient (RQ). Refinements using FOCUS and VetCalc exposure modelling software.

Toxicology Data Review

Identification of relevant toxicological endpoints No Observed (Adverse) Effect Level (No(A)EL) or Lowest Observed (Adverse) Effect Level (LO(A)EL).

User Risk Assessment / Exposure Assessment and Risk Characterisation

In accordance with the European Medicines Agency 'Guideline on User Safety for Pharmaceutical Veterinary Medicinal Products', calculation of exposure and comparison to the Margin of Exposure (MOE) sometimes called the Margin of Safety (MOS).

Global Regulatory and Environmental Strategies since 1988

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