

動物疫苗檢驗之 3R 原則導入與方法建立

動物用藥品檢定中心

柯依廷 副研究員

摘要

動物用藥品檢定中心針對各類動物疫苗之進行逐批檢驗，依據「動物用藥品檢驗標準」所列應實施項目進行檢驗。自 109 年起，基於實驗動物之取代、減量及精緻化原則，針對歷年逐批檢驗批量較多，或使用中、大型動物為試驗動物之檢驗標準進行動物疫苗檢驗技術盤點：以科學驗證方法及歷年疫苗檢驗結果為依據，評估各項檢驗標準之動物使用量之合理性，以進行動物減量；開發分子生物學技術或活體外試驗方法，取代動物試驗；並開發血清學試驗來取代動物之攻毒試驗，以減少試驗期間動物承受之痛苦。至 112 年止共有 17 項動物用疫苗檢驗標準依據 3R 原則進行制訂或修正，並完成法制作業及公告，可大幅減少逐批檢驗所需實驗動物使用量；國內動物疫苗製造廠於廠內品管檢驗時亦可遵循新修正的法規，而受惠於實驗動物減量。後續將持續盤點並投入資源進行新檢驗方法開發、國際方法導入及法規調適工作，以逐步提升檢驗品質及實驗動物福祉。

3Rs implementation in veterinary vaccine batch-inspection and method establishment

I-Ting Ko

Abstract

The Animal Drugs Inspection Branch conducts batch-by-batch testing of all types of veterinary vaccines according to the criteria outlined in the "Test Standards of Veterinary Drugs." Following the principles of replacement, reduction, and refinement (3Rs) in animal experimentation, we have implemented changes in veterinary vaccine inspection techniques since 2020, especially regarding large batch inspections or the use of medium to large animals in testing. These changes included: (1) evaluating the rationality of animal numbers used for each testing standard based on scientific validation methods and historical testing results to reduce animal usage in experiments; (2) developing molecular biology techniques or in vitro testing methods as substitutes for animal testing; and (3) establishing serological methods to replace experimental challenge tests, thereby minimizing animal suffering. By 2023, 17 sections of the Test Standards of Veterinary Drugs have been established or revised following the 3Rs principle. Legal processes and announcements have also been completed, significantly reducing experimental animal use required for batch inspections. Domestic veterinary vaccine manufacturers can also adhere to the updated regulations during in-factory quality control inspections, benefiting from reduced reliance on experimental animals. We will continue inventorying and allocating resources to develop new testing methods, adopt international standards, and adjust regulations to enhance testing quality and improve the welfare of experimental animals.