動物疫苗成品檢驗替代方法驗證項目研析

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摘要

近年國際間陸續推動以非動物替代方式進行動物用生物藥品批次檢驗，我國基於實驗動物替代原則，亦於部分動物用藥品檢驗標準章節中引用原廠開發之替代方案作為效力評估方法。為提升替代方法作為逐批檢驗效力試驗方法之公信力，本研究參考國際規範，盤點成品檢驗替代方法所須完備之確效項目，包括各項檢測用標準品之批次驗證、檢驗方法有效性之確效項目，包括特異性（specificity）、敏感性（sensitivity）、準確性（accuracy）、精確性（precision）、方法耐用性（ruggedness）等，並就實際可執行方式進行研析。針對現有之動物疫苗產品所應用之檢驗替代方法，包括抗原量檢測或抗原相對效價試驗，盤點業者提交資料中該些替代方法與疫苗效力之相關性，建立背景數據庫。後續將持續輔導業者規劃效力評估替代方案，並進行自訂檢測方法之確效，以確保後續廠內成品管制替代方法之有效性及應用於國家檢驗標準之適用性。

Study on Validation Parameters for Alternative Methods in Veterinary Vaccine Final Product Testing

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Abstract

In recent years, international trends have shifted toward utilizing non-animal alternatives for the batch testing of veterinary biologicals. Aligned with the principles of replacing animal testing, Taiwan has also incorporated manufacturer-developed alternative approaches for potency evaluation in certain chapters of the Testing Standards of Veterinary Drugs. To enhance the credibility of these alternative methods for routine batch testing, this study references international guidelines to review and identify the validation parameters required to establish alternative methods for finished product testing fully. These parameters encompass the batch validation of reference standards used in various assays, as well as analytical method validation criteria, including specificity, sensitivity, accuracy, precision, and robustness, as well as an assessment of their practical implementation. For alternative methods used in current animal vaccines (e.g., antigen quantification or relative potency tests), we reviewed the correlation between these alternatives and vaccine efficacy from data submitted by companies to build a background database. Moving forward, we will continue to assist manufacturers in designing alternative potency assessments and validating their proprietary methods, ensuring the effectiveness of in-house finished product controls and their future applicability to national testing standards.