

## 赴韓國研習動物用疫苗逐批檢驗制度及檢驗技術

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### 摘要

韓國動植物檢疫局 (Animal and Plant Quarantine Agency ; APQA) 負責動植物防檢疫與獸醫藥品管理，原亦有執行動物疫苗逐批檢驗，包括國家批次檢驗 (national lot release ; NLR) 與批次檢驗豁免系統 (NLR assay exemption ; NLRAE)，當疫苗產品通過 10 批次檢驗後，該產品可豁免逐批檢驗，改為廠商自檢，政府則透過市場抽樣確保品質。該模式大幅降低政府負擔，轉而要求廠商具備高水準的自主管理能力。

韓國計畫於 2025 年推行的種毒批次管理制度 (seed-lot system ; SLS)，要求疫苗生產者提交種毒與細胞庫的詳細技術數據，確保品質穩定。該計畫規劃以 7 年分階段推動，期望未來可減少最終產品品質的檢驗需求，提升國際競爭力並減少實驗動物的使用。

韓國的動物用疫苗管理制度在逐步減少逐批檢驗、強化廠商自主管理方面值得我國參考，然而其即將實施的種毒批次管理制度雖有助於提升動物疫苗品質，但對業者的影響仍待觀察。本次研習建立了與 APQA 的聯繫管道，未來將持續關注其政策發展，作為國內動物疫苗檢驗制度改革的借鏡。

# **Study in South Korea on the Batch Inspection System and Testing Techniques for Veterinary Vaccines**

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## **Abstract**

The Animal and Plant Quarantine Agency (APQA) of Korea is responsible for animal and plant quarantine and managing veterinary drugs. It has also implemented a batch-by-batch inspection system for veterinary vaccines, including the national lot release (NLR) and the NLR assay exemption (NLRAE) system. Under this system, vaccine products that pass ten consecutive batch inspections are exempted from further batch-by-batch testing, allowing manufacturers to conduct self-inspections, while the government ensures product quality through market sampling. This model significantly reduces the government's burden while placing higher demands on manufacturers for self-regulation.

Korea plans to introduce the seed-lot system (SLS) in 2025, requiring vaccine manufacturers to submit detailed technical data on vaccine seeds and cell banks to ensure product quality and consistency. This system is designed to be implemented in phases over seven years, to reduce final product quality control testing, enhance international competitiveness, and minimize the use of laboratory animals.

Korean veterinary vaccine management system, which progressively reduces batch-by-batch inspections while strengthening manufacturers' self-regulation, serves as a valuable reference for our country. However, the impact of the upcoming seed-lot system on the industry remains to be observed. This training program has established a communication channel with APQA, and future developments in its policies will continue to be monitored as a reference for the reform of our domestic veterinary vaccine inspection system.