獸醫基因改造產品試驗設施之運轉與對外服務

動物用藥品檢定分所

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摘要

為了我國獸醫基因改造產品之研發、管理並建立具科學依據之安全評估系統，動物用藥品檢定分所於民國 94 年完成獸醫基因改造產品動物舍之建置，並逐年強化設施的品質管理、硬體維護及人員訓練，以作為獸醫基因改造產品於研發階段或產品登記階段之隔離動物試驗場所。本設施為雙回廊設計之負壓生物安全二級動物舍，共有 12 間動物室，依據相關規範嚴格執行生物安全管控。自 97 開始對外服務至今，共計完成 24 項法定委託試驗、72 項疫苗開發前期評估試驗、13 項生技產業之研發試驗、以及 207 項例行疫苗檢驗。每年並持續執行設施內設備確效及環境監控、逐年汰換或更新設施運作所需之設備、配合委託方建立新型飼養管理模式以及導入生物風險管理系統。本設施將持續在既有之基礎上就獸醫基因改造產品為產業提供完善服務，並持續就成本、收入及設施使用率之間進行檢討，取得平衡以達到永續營運目標。

Operation of an animal testing facility for genetically modified veterinary products

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Abstract

In order to develop, manage, and establish a scientifically-based safety evaluation system for genetically modified (GM) veterinary products, the Animal Drug Inspection Branch (ADIB) built an animal testing facility in 2005. The facility has continually improved in its mission to conduct research on, and registration of GM veterinary products, by implementing quality management and equipment maintenance systems as well as personnel trainings throughout the years.

This facility is a negative pressure bio-safety secondary animal house that is designed with double corridors and 12 animal rooms. The facility strictly implements bio-safety control procedures and workflows in accordance with the relevant regulations. Since 2008, the facility has completed 24 new animal biological product trials, 72 pre-development evaluation tests of animal vaccines, 13 R&D trials from the biotechnology industry, and 207 routine vaccine inspections.

Every year, the facility performs a routine equipment, instrument, and environmental assessment, as well as updates equipment as necessary, reassesses the animal management program, and assesses the biological risk (via a recently introduced biological risk management system). The facility will continue to provide comprehensive services for the testing of GM veterinary products on an established basis, and will continue to review the costs, revenue and facility usage to achieve the most efficient use of its services.