動物用生物藥品國家檢定實驗室管理制度建立及經驗分享

動物用藥品檢定分所

葉修如 研究員兼分所長

摘要

動物用生物藥品檢驗係依據動物用藥品管理法第 18 條，於製成或輸入報關完稅後，應逐批申請抽樣檢驗，查驗合格封籤後始得出售，使畜禽產業使用安全且具合格功效之動物疫苗，預防動物疫病，維持產業防疫安全。行政院農業委員會家畜衛生試驗所動物用藥品檢定分所生物藥品檢定研究系(以下簡稱生檢系)是我國唯一執行動物疫苗國家級檢定單位，具有完備之實驗室及動物試驗設施，每年檢驗動物疫苗 1,000 批以上。為使疫苗檢驗品質更有保障，生檢系自民國 93 年通過國際規範 ISO 17025 認證以來，推動實驗室品質與檢驗全面遵循認證規範，對於以檢驗測試為主要任務之實驗室管理系統建立，以及檢驗技術系統提升，有極大的幫助。後續將動物舍管理逐步納入 ISO 17025 系統，動物舍管理也提升到符合國際規範要求之水準。惟制度導入並非一蹴可及，且動物疫苗檢驗項目繁雜，如何將一個品質制度導入以測試為主要任務的實驗室，茲分享經驗如下：1、檢驗工作的主體是工作人員，因檢驗項目繁多、數量龐大，須所有成員團隊合作才能完成，維持人員間良好的溝通是首要任務。2、實驗室人員

異動常造成技術斷層，落實代理人制度及技術查核是實驗室技術傳承的重點。3、例行檢驗工作以平台方式運作比個人運作效率佳。4、先求「有」再求「好」，逐步落實，形成制度。5、管理階層的支持，制度才能持續維持。

Lessons learned from the establishment of a national laboratory for the management and inspection of biopharmaceutical products

Shiu-Ru Yeh

Abstract

According to Article 18 of the Animal Drug Administration Law, a batch-by-batch inspection system is needed for safety and effectiveness of all biopharmaceutical products after production or import. All animal vaccines on the market thus need to be inspected so that the animal industry is operating safely and efficiently. The Department of Biologics Assay and Research (DBAR) of the Animal Drug Inspection Branch is the only national organization with complete laboratory and animal facilities for the inspection of animal vaccines. More than 1,000 animal vaccine batches per year are routinely inspected. Since the implementation of the ISO 17025 international certification standards for vaccine testing in 2004, the DBAR has visibly improved testing quality, laboratory management, and technical system testing, The animal housing facilities and their management were also gradually upgraded to meet the requirements of the ISO 17025 international certification standards. However, the implementation of the system has not fully accomplished since the animal vaccine testing program is complicated. To proceed further we suggest the following considerations for introducing a quality management system into testing laboratory environments. 1. Since the main part of the inspection work is conducted by human personnel and the work load is large, large teams must establish and maintain clear lines of communication. 2. Laboratory personnel turnover and shift changes often lead to technical mistakes such that the proper implementation of a substitute system and technical control checks are needed. 3. Platform-based operations are more efficient than personnel-based operations. 4. Improve quality incrementally. 5. With proper support of competent management, a proper inspection regime can be sustained.