2011-2015 年生物製劑品管檢驗工作報告

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摘要

本所自 1988 年建立符合 GMP 規範之藥廠，本組主要負責家畜禽疫苗及診斷試劑之改良與開發並製造疫苗、儲備與供應。本所擁有 20 張生物製劑製造許可證，分析自 2011 年至 2015 年 9 月品質管制資料，主要生產的產品包括雞新城病病毒紅血球凝集抗原（4 批：合格率 100%）、乾燥兔化豬瘟毒種毒（7 批：合格率 100%）、雛白痢診斷液(11 批:合格率 100%)、乾燥兔化豬瘟疫苗(63 批:合格率 100%)、豬假性狂犬病不活化疫苗（5 批：合格率 100%）、牛流行熱不活化疫苗(11 批:合格率 100%)、水禽小病毒活毒疫苗(6 批:合格率 100%)、羊痘活毒疫苗（4 批：合格率 100%）、石斑魚虹彩病毒不活化疫苗（2 批：合格率 100%）、水禽雷氏桿菌症不活化菌苗 (第 1、2 和 6 血清型)（2 批：合格率 100%），每年共有二十餘批之不同製劑生產，提供國內防疫及診斷之用。另為提升藥品品質，增加國際競爭力，推動藥品實施 cGMP 確效作業亦是將來的趨勢。

Quality Control Inspection of Biologics for 2011-2015

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Abstract

The pharmaceutical factory of the Animal Health Research Institute of Taiwan (AHRI) was established in accordance with the Good Manufacturing Practice (GMP) standard in 1988. The main task of the biologics division is production, development, storage and supply of vaccines and diagnostic reagents. AHRI possesses 20 manufacture licenses for animal biologics. We analyzed the quality control data collected from 2011 to Sept. 2015, that include Newcastle disease hemaggluutination antigen (4 batches, percent of pass: 100%), frozen-dried lapinized hog cholera seed virus (7 batches, percent of pass: 100%), pullorum disease antigen (11 batches, percent of pass: 100%), frozen-dried lapinized hog cholera vaccine (63 batches, percent of pass: 100%), swine pseudorabies inactivated vaccine (5 batches, percent of pass: 100%), bovine ephemeral fever inactivated vaccine (11 batches, percent of pass: 100%), waterfowl parvovirus live vaccine (6 batches, percent of pass: 100%), goat pox attenuated live vaccine (4 batches, percent of pass: 100%), grouper iridovirus inactivated vaccine (2 batches, percent of pass: 100%), RA trivalent inactivated bacterin (serotpye 1, 2 and 6; 2 batches, percent of pass: 100%), among others. More than 20 different batches of biologics manufactured are provided for disease control and diagnostics. In order to improve the quality of animal biologics produced in Taiwan and the international competitiveness of our services, the implementation of process validation in pharmaceutical factories that are conformed to current Good Manufacture Practice (cGMP) is a must.