2020-2021 年生物製劑品管檢驗工作報告

製劑研究組

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摘要

本所自 1988 年建立符合 GMP 規範之藥廠，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。目前本所擁有 21 張生物製劑製造許可證，主要生產的產品包括雞新城病病毒紅血球凝集抗原、雛白痢診斷液、牛流行熱不活化疫苗、豬瘟組織培養活毒疫苗、水禽小病毒活毒疫苗、羊痘活毒疫苗、水禽雷氏桿菌症不活化菌苗 (第 1、2 和 6 血清型)等。分析自 2020 年至 2021 年資料，每年約有十餘批之不同製劑生產，提供國內防疫及診斷之用。

Quality Control Testing of Biologics from 2020-2021

Cheng-chu Hsieh

Abstract

In 1988, the Animal Health Research Institute (AHRI) established a pharmaceutical factory that complied with international GMP standard requirements. The main tasks of the biological products division are the production, development, storage and supply of vaccines and diagnostic reagents. AHRI currently possesses 21 manufacturing licenses for various biological animal products including a Newcastle disease hemaggluutination antigen, a pullorum disease antigen, a bovine ephemeral fever inactivated vaccine, a hog cholera tissue culture live vaccine, a waterfowl parvovirus live vaccine, a goat pox attenuated live vaccine, and *Riemerella anatipestifer* (RA) inactivated trivalent bacterins (serotpye 1, 2 and 6). An analysis of data from 2020-2021 showed that more than 10 different batches of biological preparations are manufactured each year. Each batch was certified for quality control and national inspection, thereby safely ensuring domestic epidemic prevention and diagnosis.