2018-2019 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、乾燥兔化豬瘟毒種毒、雛白痢診斷液、乾燥兔化豬瘟疫苗、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、石斑魚虹彩病毒不活化疫苗、水禽雷氏桿菌症不活化菌苗 (第 1、2 和 6 血清型)等。分析自 2018 年至 2019 年資料，每年約有二十餘批之不同製劑生產，每批皆符合自家品管及國家檢定合格，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，於 2020 至 2023 年「建置動物用疫苗先導工廠」，規劃符合 PIC/S GMP 藥廠規範，使產程優化及提高生產品質，將帶動國內動物疫苗產業的發展。

Quality Control Testing of Biologics from 2016-2017

Cheng-chu Hsieh

Abstract

In 1988, we established a pharmaceutical factory at the Animal Health Research Institute (AHRI) that complied with 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 Newcastle disease hemagglutination antigen, freze-dried lapinized hog cholera seed virus, pullorum disease antigen, frozen-dried lapinized hog cholera vaccine, bovine ephemeral fever inactivated vaccine, hog cholera tissue culture live vaccine, waterfowl parvovirus live vaccine, goat pox attenuated live vaccine, grouper iridovirus inactivated vaccine, and *Riemerella anatipestifer* (RA) inactivated trivalent bacterins (serotype 1, 2 and 6), among many others. An analysis of data from 2018-2019 shows that more than 20 different batches of biological preparations were manufactured each year, and each batch passed quality control and national inspections, thereby supporting domestic epidemic prevention and diagnostic efforts. To further improve the quality of biological animal products manufactured in Taiwan as well as their international competitiveness, we plan to “build a pilot plant for animal vaccines” from 2020-2023, which will comply with PIC/S GMP pharmaceutical factory standards, and drive indusrial animal vaccine development in Taiwan.