2022~2024 年生物製劑品管檢驗工作報告

製劑組

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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、羊痘活毒減毒疫 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2022 年至 2023 年生物製劑生產資料, 2022 年共生產 7 批, 2023 年共生產 8批,檢測結果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。另為提升細胞培養疫苗產量改善,製程優化及提高生產 品質,供儲備或緊急疫苗之製備,本所於 2023 至 2024 年間,將原乾 燥兔化豬瘟疫苗製造區改建為細胞培養疫苗量產製程區。以期未來可 配合產、官、學,協助將研發的細胞培養疫苗從實驗室產量擴增為商 品化生產,銜接實驗室之開發與商品化之間的鴻溝,推動我國動物用 藥品的發展。

Quality Control Inspection of Biologics During 2022-2024

Cheng-chu Hsieh

Abstract

In 1988, we established a pharmaceutical factory, which complied with the GMP standard requirements at the Veterinary Research Institute (VRI). The main tasks are to produce, to develop, to store and to supply vaccines and diagnostic reagents. VRI currently possesses 21 manufacturing licenses for various biological animal products including Newcastle disease hemaggluutination antigen, pullorum disease antigen, bovine ephemeral fever inactivated vaccine, goat pox attenuated live vaccine, and Riemerella anatipestifer (RA) inactivated trivalent bacterins (serotype 1, 2 and 6), among many others. Analysis of biological product production data from 2022 to 2023, a total of 7 batches were produced in 2022, while in 2023, the number increased to 8 batches. Each batch passed the internal quality control and the national inspection tests, meeting the requirements for domestic epidemic prevention and diagnosis. Furthermore, to enhance the yield of cell culture vaccines, to optimize the production process, and to improve product quality for reserves or emergency vaccine preparation, the area previously used for frozen dried lapinized hog cholera vaccine production went under renovation. This area is being converted into a large-scale cell culture vaccine production zone during 2023 to 2024. The renovation aims to bridge the gap between laboratory research and commercial production by collaborating with industry, government, and academia. This will facilitate the scaling up of cell culture vaccines from experimental production to commercial manufacturing, advancing the development of veterinary pharmaceuticals in our country.