

# 豬環狀病毒次單位疫苗效力試驗以及赴日本京都參訪微生物化學研究所出國報告

製劑研究組  
施雨華 助理研究員

## 摘要

豬環狀病毒第二型(porcine circovirus type 2; PCV2)是引起豬環狀病毒症(Porcine circovirus disease; PCVD)的主要病原。本實驗以昆蟲細胞表現的PCV2 ORF2次單位蛋白疫苗，進行3批豬隻疫苗效力試驗。結果顯示免疫組豬隻經疫苗免疫後，間接螢光抗體檢測抗體力價可達 $256X \sim 4,096X$ 。而在攻毒後以real-time PCR檢測豬隻血清以及各臟器之PCV2病毒核酸量，顯示為免疫對照組血清中核酸量可達 $5.0 \times 10^{8.15}/\text{mL}$ ，免疫組則小於 $1 \times 10^{6.15}/\text{mL}$ 。另外未免疫對照組豬隻於腸系膜淋巴結的copy number可達 $1.8 \times 10^{8.15}/\text{mL}$ ，至於疫苗免疫組則無法偵測到PCV2核酸，此動物試驗結果顯示PCV2次單位疫苗能產生良好的保護力。

本組派員於105年11月28日至12月2日赴日本參訪京都微生物化學研究所，藉由本次的參訪了解國際疫苗廠內部建構、製程、疫苗品管與研發等運作模式。參訪同時蒐集日本動物疫苗產業現況與疫苗使用現況相關訊息，有助於檢視我國動物疫苗產業現況，以及未來發展之方向。

# Efficacy Tests on Porcine Circovirus Type 2 Subunit Vaccine

## /Report of Visiting KyotoBiken Laboratories

Yu-Hua Shih

### **Abstract**

Porcine circovirus type 2 (PCV2) is the main pathogen causing porcine circovirus disease (PCVD). In this study, the PCV2 ORF2 subunit vaccines were expressed and produced in insect cells, and three animal trials were tested for efficacy study on swine. The results showed that the IFA (indirect fluorescent antibody test) antibody titers have reached 256X-4,096X in the immunized swine. The detection of virus DNA copies in sera and organs with realtime RT-PCR after challenge have demonstrated that as high as  $5.0 \times 10^{8.15}/\text{mL}$  was found in the non-vaccinated control group, whereas less than  $1 \times 10^{6.15}/\text{mL}$  was found in the immunized group. In addition, the virus DNA copies  $1.8 \times 10^{8.15}/\text{mL}$  was detected in the mesenteric lymph nodes of non-vaccinate control group, but none was detected in the vaccine group. In conclusion, these trials results indicated that this PCV2 ORF2 subunit vaccine developed by AHRI could provide satisfactory protection.

Two researchers were dispatched to visit KyotoBiken Laboratories in Japan from November 28 to December 2 in 2016. Through the visit of this international vaccine factory, the author has gained general knowledge of the factory construction, production process, quality control and research and development of vaccines. In addition, the information of current status in Japanese animal vaccine industry and use of animal vaccines were collected. These finding may help review the status of animal vaccine industry in Taiwan and the future direction of vaccine development.