

# 應用 ISO 9001 品質管理系統提升實驗動物生產效能及品質

動物用藥品檢定分所實驗動物研究系

江俊儀 助理研究員

## 摘要

畜衛所動物用藥品檢定分所其中一項業務職掌即為生產 SPF 胚蛋雞雞及生醫用清淨兔，自民國 98 年引進 ISO 9001 品質管理系統後，隨即進行最高管理層、政策和質量目標的定義，並調查繁殖動物設施關鍵點，完成文件制訂和人員培訓，並於民國 99 年通過驗證，經過多年不斷修制訂程序、人員教育訓練及落實管理系統，檢定分所生產的無特定病原胚蛋保證未攜帶病原種類由早期的 14 種逐年提升至 18 種。且在有限資源下，每年亦可多提供 3000 枚 SPF 胚蛋進行動物疾病檢診、生醫藥各項試驗研究及疫苗製造。不僅如此，生醫用兔於管理系統的落實運作下，離乳仔兔育成率提升了 23%，嚴重影響兔隻健康的腦炎小胞蟲感染亦降低了 27% 的發生率，大大提升生醫用兔品質。由此可知，將 ISO 9001 品質管理系統應用於 SPF 胚蛋及生醫用兔生產，可有效提升其生產效能及品質。

# **Application of the ISO 9001 quality management system at laboratory animal breeding facilities improves the production efficiency and quality of laboratory animals**

Chiang chun yi

## **Abstract**

Production of specific pathogen-free (SPF) chickens, embryonated eggs and clean conventional rabbits is an important mission and service of the Animal Drug Inspection Branch (ADIB), within the Council of Agriculture's Animal Health Research Institute. In order to improve the production efficiency and quality of laboratory animals, the ISO 9001 quality management system (QMS) was implemented at ADIB in 2009. As a result of this implementation, ADIB has been more effective in highlighting important topics for management, defining policy and quality control objectives, monitoring critical points at animal breeding facilities, defining structural work, completing and updating important documents, and in training staff. ADIB was officially ISO 9001 certified in 2010. As a result of continuous SOP revision, staff training and QMS implementation, SPF chickens and embryonated eggs now test negative for 18 agents. Furthermore, 3,000 additional SPF eggs are supplied each year for the purpose of animal disease diagnostics, animal drug inspections, as well as for research and vaccine production purposes. The production efficiency and quality of clean, conventional rabbits have also been improved, such that the post-weaning survival rate has increased by 23% while at the same time the infection rate of *Encephalitozoon cuniculi* decreased by 27%. These results demonstrate that the implementation of the ISO 9001 QMS greatly facilitated the improvement of production efficiency and the quality of SPF chickens, embryonated eggs and clean conventional rabbits.