開發基因改造動物用生物藥品安全性評估及風險管理技術

動物用藥品檢定分所

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摘要

面對國際間逐年增加之新型基因改造動物用生物藥品，國內需建立對應之安全性評估試驗模式，並強化國際資訊蒐集，確保檢驗技術能與國際同步。本研究完成收集歐盟及美國基因改造動物用生物藥品安全性評估相關規範，並就近年審查之第三類基因改造動物用生物藥品之文件及試驗，盤點我國基因改造動物用生物藥品檢驗技術缺口。後續完成第三類基因改造疫苗之對象動物排毒途徑試驗、組織向性試驗、毒力迴歸試驗、基因穩定性體外試驗、環境中存活力之評估試驗以及環境中散布能力試驗等模式之建立，執行期間陸續建立基本試驗技術及相關標準作業程序，並透過教育訓練培養團隊中之專業技術人力，期能運用於往後基因改造活毒疫苗新藥評估試驗，以有效解決目前我國基因改造動物用生物藥品風險評估技術缺口，提升我國基因改造動物用生物藥品產業之國際競爭力，同時提供試驗基礎資料供主管機關未來研擬相關法規時參考依據。

Development of Safety Assessment and Risk Management Techniques for Genetically Modified Animal Biologics

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Abstract

In order to effectively manage genetically modified (GM) animal biologics, the establishment of safety assessment techniques is urgent. Moreover, strengthening international guidelines collection can ensure that inspection technology is consistent with international standards. In order to identify the gaps in effective technical inspections, we completed the collection of European Union and United States standards for the safety assessment of GM animal biologics and inventoried the recently reviewed documents and tests of these GM animal biologics. According to the results of the inventory, we established several safety assessment models including those that evaluate tissue tropism, transmission routes, virulence regression *in vivo*/*in vitro*, as well as environmental survival and spread. Furthermore, we also set up standard analytical techniques while also training technical staff in standard operating procedures. We have effectively used risk assessment to identify and address the current gaps in effective technological monitoring of GM animal biologics, and this will enhance the international competitiveness of the domestic biopharmaceutical industry involved in the production of veterinary GM products. The related research achievements can also be used as references when authorities draft future regulations.