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動物用一般藥品檢驗登記品質技術文件審查簡介

動物用藥品檢定中心

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摘要

動物用藥品檢定中心職司動物用藥品國家檢驗工作，除檢驗工作外，還需進行檢驗登記品質技術文件（Quality Technical Document, QTD）審查工作。本次主要介紹動物用一般藥品檢驗登記之品質技術文件審查概要，內容涵蓋品質技術文件範圍、法規依據、審查方式、審查統計及常見缺失與案例說明。

首先介紹品質技術文件範圍，審查文件所依據的法規，概述我國現行動物用藥品檢驗登記法規架構，包含主管機關規範及國際標準。其次說明審查方式及審查重點，並介紹審查邏輯。審查統計則提供2021-2024年動物用一般藥品QTD審查案件之數據統計，包括審查件數、補件數與常見缺失統計，供業界參考。

最後針對常見缺失及案例進行說明，列舉企業在申請過程中經常遭遇的問題，如資料不完整、試驗數據不足及規範適用錯誤，並提供具體案例與改進建議，加速審查流程。

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Introduction to the Inspection of Quality and Technical Documents for the Registration of Veterinary Chemical Drugs

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Abstract

The Animal Drugs Inspection Branch is responsible for the national inspection of veterinary drugs. In addition to laboratory inspection work, it also conducts the document inspection of Quality Technical Documents (QTD) for veterinary drug registration. This presentation provides an overview of the inspection process for QTDs in the registration of veterinary chemical drugs, covering the scope of QTDs, regulatory basis, review methods, review statistics, common deficiencies, and case studies.

First, the presentation introduces the scope of QTDs and the regulations governing the review process. It provides an overview of the current regulatory framework for veterinary drug registration in the country, including government regulations and international standards. Next, it explains the review methods and key points of assessment, along with the logical approach applied in the review process.

The review statistics section presents data on QTD inspection in recent years, including the number of cases reviewed, requests for supplementary documents, and common deficiencies encountered. This serves as a reference for the industry.

Finally, the document discusses common deficiencies and case studies, highlighting frequent issues encountered during the application process, such as incomplete documentation, insufficient test data, and misapplication of regulations. It also provides specific case examples and improvement recommendations to facilitate a more efficient inspection process.