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Storing and Transporting Cell Therapy Specimens and Products

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Abstract

After the enactment of the Regulations Governing the Application or Use of Specific Medical Techniques or Examinations, or Medical Devices, many medical institutions have introduced medical techniques specific to cell therapy. To ensure the safety of cell therapy, human tissue or blood specimens and cell products must be stored and transported at low temperature throughout the entire process and continuously monitored for their temperature. The tissue, specimens, and products must have their expiration dates and storage conditions labeled clearly and completely. Cell products that are damaged or transported without meeting the temperature requirements must be destroyed. To prevent the potential hazards of cell therapy and thus ensure patient safety, medical institutions conducting cell therapy must establish procedures for reporting and handling adverse events.

Keywords: cell therapy; Regulations Governing the Application or Use of Specific Medical Techniques or Examinations, or Medical Devices; specimen transportation; cell product transportation; continuous temperature record

細胞治療檢體及成品的儲存與運送

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摘要

細胞治療在國內的特管辦法施行後，陸續吸引了許多醫療院所引進相關的特定治療技術。為確保細胞治療的安全性，必須確保人體組織或血液檢體與細胞製品的儲存及運送過程全程低溫，且有連續的溫度監控。人體的組織或血液檢體與細胞製品必須有清楚且完整的效期及儲存條件的標示。若細胞製品發生損壞或運送過程中溫度未達要求，應進行細胞製品的銷毀。為確保病人接受細胞治療的安全性，執行細胞治療的醫院應設置異常事件的通報及處理流程，以避免對病人造成危害。

關鍵詞：細胞治療、特管辦法、檢體運送、細胞製品運送、連續溫度紀錄