

The Management Status of Human Tissue Banks in Taiwan

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ABSTRACT

The progress of human stem cells research and tissue engineering has gradually boosted the recovery, screening, processing, storage, culture and distribution of human organs, tissues and cells used in transplant, into an emerging interdisciplinary biotechnological industry in many countries.

However, the biggest risk for human tissue is the introduction, transmission or spread of communicable diseases caused by improper processing. These risks affect its integrity and effectiveness. In order to fulfill the management requirement for human tissue usage, the Center for Biologics Evaluation and Research of U.S. Food and Drug Administration has formally announced Code 21 CFR 1271 on May 25, 2005, along with the current good tissue practice for administering collection, process and transport of human cells and tissues accordingly. Due to the latest international management trends and needs for domestic industry, Department of Health, Taiwan has formally announced regulations for administration on human organ bank in Feb. 2009, in which article 12: "The establishment and operation of an organ bank shall comply with the rules of good human organ, tissue and cell practice" is the guideline for establishments in research and manufacture to follow. As of the end of 2010, 111 organ banks have filed application, 99 have been reviewed, 83 have applied for on-site inspection, 48 have been inspected, and 28 have been approved. To promote the quality of establishments in human organ bank, Taiwan Food and Drug Administration will continually conduct the conformity identification process and set up the registered certification system, so as to ensure the safety for recipient to accept organs, tissues and cells.

Key words: human tissue bank, tissue engineering, risk