The Inspection Management of Human Cell, Tissue, and Cellular and Tissue-Based Products in Taiwan

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ABSTRACT

The biggest risk for human cell, tissue, and cellular and tissue-based products (HCT/Ps) is the introduction, transmission or spread of communicable diseases caused by improper processing. These risks affect its integrity and effectiveness. In order to reduce the risk for HCT/Ps usage and to follow the latest international management trends, Department of Health, Taiwan formally announced good tissue practice (GTP) in Dec. 2002. The GTP is the guideline for establishments in research and manufacture to follow. The regulations for administration on human organ bank were then announced by Department of Health, Taiwan in Feb. 2009. It is the regulations for institutions that are engaged in the processing or preservation of human organs, tissues and cells for the purpose of transplantation to follow. Sixty-four human trials have been inspected according to GTP from 2005 to 2011. As of the end of 2011, 114 organ banks have filed application, 102 have been inspected, and 92 have been approved. To reduce the risk for HCT/Ps usage, Taiwan Food and Drug Administration will continually conduct the conformity identification process, so as to ensure the safety and quality for regenerative medicine.

Key words: human cell, tissue, and cellular and tissue-based products, good tissue practice, cell therapy, human tissue bank