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The regulation of allogeneic human cells and tissue products as biomaterials

Kazuo Yano and **Masayuki Yamato** Tokyo Women's Medical University, Japan

The current definition of biomaterials differs vastly from it of just a decade ago. With advanced new technology and the scope in the domain of healthcare, it encompasses unpredictable materials such as engineered human cell and tissue. These biomaterials also have to be approved to use in healthcare business by regulatory authority, which are defined as drug, medical devices, or biologics in the regulation. The pathways of seven approved allogeneic human cells and tissue products for market authorization in the United States were four in PMA, one in HDE and two in BLA until March 2012. Six allogeneic human cells and tissue products derived from neonatal or infant fibroblasts and/or keratinocytes were approved as medical devices or biologics as well as hematopoietic progenitor cells of cord blood. For five of seven human cells and tissue products, well-controlled comparative clinical trials were conducted as pre-approval evaluation followed by post-approval evaluation. Although these products avoid a sterilization process usually used for medical devices, no serious malfunction that would lead to class 1 recall was reported. After premarket approval (PMA), any PMA holder has to PMA supplement that meets any change that affects or enhances the safety and effectiveness of the medical devices. Since allogeneic cell sources would enable to produce large-scale lots of products having well-controlled quality with lots of products, they can establish business model that brings profits. In the future, it is widely expected that various kinds of allogeneic human cells and tissue products would be on market.

Biography

Kazuo Yano received his PhD from Cooperative Graduate School of Tokyo Women's Medical University and Waseda University. He is working as a part time Assistant Professor at both Universities. He has published 14 papers in journal and has been an international member of ISO 14155 (Global GCP Standard of Medical Device).

yano.kazuo@twmu.ac.jp yamato.masayuki@twmu.ac.jp

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