

European Pharma Congress August 25-27, 2015 Valencia, Spain

Regulatory approval for autologous human cells and tissue products in the United States, the European Union, and Japan

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

Since human cells and tissue products belong to a relatively new class of medical products, limited information is available on the Classification and premarket evaluation of human cells and tissue products in the United States (US), the European Union (EU), and Japan. We surveyed the definition, legislation, and approval system of a total of nine autologous human cells and tissue products in October 2013. The definition ofhuman cells and tissue products were compatible among the US, the EU, and Japan. The products were categorized as human cells, tissue, and cellular and tissue-based products (HCT/Ps) in the US, advanced therapy medicinal products (ATMPs) in the EU, and cell/tissue-engineered products (currently regenerative therapy products) in Japan. Autologous human cells and tissue products were handled administratively as "accelerated approval of biological product," "humanitarian device exemption (HDE) approval," "premarket application (PMA) approval," "biologics license application (BLA) approval," and "new drug application approval with specific targeting of post-approval registry or surveillance. Of nine autologous human cells and tissue products, four products had been evaluated using clinical experiences or open clinical trials with a small number of subjects, although the other products had been evaluated using comparative clinical trials with control treatment. The clinical evaluation of autologous human cells and tissue products would focus on post-market-oriented evaluation rather than premarket-oriented evaluation. We should consider that the premarket clinical evaluations of these products need to use not only clinical experience but also historical control data, and to use adaptive licensing for approval system.

Biography

Kazuo Yano received his PhD from Cooperative Graduate School of Tokyo Women's Medical University and Waseda University. He is 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). Masayuki Yamato received his PhD from Graduate School of Arts and Sciences, University of Tokyo. He is the Director of Institute of Advanced Biomedical Engineering and Science, Tokyo Women's Medical University. He has published more than 500 papers in journal and has been servicing as an Associate Editor of *Regenerative Therapy*.

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

Notes: