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総 説

ヒト多能性幹細胞由来の再生医療製品開発における造腫瘍性評価に関する日米欧三極の規制の状況

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Current Status of Regulatory Policies on Evaluation of Tumorigenicity for Pluripotent Stem Cell-derived Products at the Development Stage — on Japan, US and EU

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Summary

Tumorigenicity is one of the major concerns for a medical use of pluripotent stem cell-derived products (PSCPs). However, no detailed guidance document for evaluating and assessing the tumorigenicity of PSCPs has been issued. Internationally acceptable concepts/consensus and testing methods for reduction in the tumorigenicity risk of PSCPs are needed, in particular when PSCPs are intended to be globally distributed. Forum for innovative regenerative medicine (FIRM) has established a new committee, FIRM-CoNCEPT, to address the issues around tumorigenicity evaluation for PSCPs. FIRM-CoNCEPT and National Institute of Health Sciences (NIHS) jointly started "*Multisite Evaluation Study on Analytical Methods for Non-clinical Safety Assessment of hUman-derived REgenerative Medical Products* (MEASURE)" initiative. International regulatory policies on the safety evaluation and quality control and methods of hazard/risk assessment for tumorigenicity are investigated in the project. As the results, we found 3 points below. 1) Several *in vivo* and *in vitro* assays are available. 2) Japanese technical guideline is available for PSCPs. However, globally acceptable consensus in regulatory policies are not observed among Japan, US and EU. 3) By making key opinion leader (KOL) interviews, evaluation methods for genomic instability risk of PSCPs were found unestablished. The purpose of this article is to summarize and publish the output of investigation and discussion which were made in FIRM-CoNCEPT-MEASURE project.

Key words

Pluripotent stem cell, Tumorigenicity, Testing method, FIRM, CoNCEPT, MEASURE