MF4MPS (Microfluidics Project for MPS) Establishment Purpose

Microfluidics technology has many applications, but in recent years it is rapidly gaining attention for use in micro-physiological systems (MPS), which reconstruct a culture environment similar to that of a living organism (*in vivo)* in a small space and enable the creation of *in vitro* culture systems that can be used for toxicity, safety, and efficacy testing of drugs in various modalities. MPS is an *in vitro* culture system that is being considered for application to toxicity, safety, and efficacy testing of pharmaceuticals. Japan, the world's pioneer in the development of iPS cells, possesses the technology that can, in principle, produce all types of human cells used in MPS. In addition, Japan possesses the advanced technologies for materials such as plastic and rubbers used in microfluidics and their microfabrication technologies, which it has cultivated through the development and manufacture of industrial products and is ready for making international contributions.

MPS has also received a great deal of attention as an alternative to animal testing, as the U.S. Environmental Protection Agency (EPA) announced in 2018 that it would discontinue conducting research using mammals and providing funding for such research by 2035, and in December 2022, the U.S. President signed into law the FDA Modernization Act 2.0, which explicitly states the use of alternative methods for animal testing, including MPS. In December 2022, the FDA Modernization Act 2.0 was signed into law by the President of the United States, which explicitly states that the use of alternative methods for animal testing, including MPS, is an alternative to animal testing. In addition to this, the original advantage of MPS is that it allows the use of human cells, and therefore, it is possible to conduct evaluation studies of the efficacy and safety of drugs in humans that could not be conducted in animal experiments.

Furthermore, the international market for microfluidics, the basic technology for MPS, is expected to grow in relation to regulations for pharmaceuticals and other products and is forecast to reach $50,934.63 million (approximately 70 trillion yen) by 2027, with an average growth rate of 17.5% between 2022 and 2027*1.
1 Global Microfluidics Market (2022-2027), Mordor Intelligence (2021)

In order to realize MPS, for which a large market is expected in the future, it is essential to integrate cell culture technology, which handles cells, with engineering technologies such as material technology and microfabrication technology, and to formulate rules, including

standards, for the international community. International standardization related to MPS has already begun, mainly in Europe, and there are high expectations for Japan. Therefore, in order for Japan to establish cooperation with these standardization activities and to continue standardization and development in international collaboration, we have established the project "MF4MPS (Micorfluidics for Microphysiological System). The project MF4MPS is hereby declared to be organized and to start activities in order to establish and to continue standardization and development of these standardization activities in international cooperation.