公益財団法人
京都大学 iPS細胞研究財団

Press Release

CiRA Foundation obtained manufacturing license based on the PMD Act

Kyoto, Japan, 18 January 2021 – On 15th January, the CiRA Foundation (CiRA_F) has obtained a manufacturing license (general category) for regenerative medicine products based on the Pharmaceutical Affairs and Medical Devices Act (PMD Act) in Japan.

The application for this manufacturing license was submitted to the Kinki Regional Bureau of Health and Welfare on June 24, 2020. With this license, we are now able to manufacture and store regenerative medicine products that can be marketed under the PMD Act.

We have already been manufacturing and storing clinical trial products and have permission to manufacture “specified cell processing products” based on the Act on the Safety of Regenerative Medicine. In addition, we have manufactured and stored specified cell processing products for use in clinical research, such as iPS cells, iPS cell-derived platelets, and iPS cell-derived neuronal cells.

By obtaining a manufacturing license based on the PMD Act, we can further expand the range of collaboration with companies and contribute to the development of the regenerative medicine industry. More importantly, we will continue to make every effort to realize our foundation's philosophy of "provide the best iPS cell technology with affordable price."

About the CiRA Foundation

Recognized as a public interest incorporated foundation in April 2020, it manages the iPS Cell Stock for Regenerative Medicine Project, which was started by the Center for iPS Cell Research and Application (CiRA), Kyoto University, in 2013. The aim of this project is to prepare multiple clinical-grade iPS cell lines manufactured from healthy donors homozygous for human leukocyte antigens (HLA). These lines will expand the number of people who can receive related therapies with minimal immune reactions and are provided to academia and industry. The Foundation also contributes to the commercialization of regenerative medicine by providing services including the manufacturing of iPS cell-derived products, quality assessment, storage, and publication of SOPs for manufacturing.

Contacts:
Public Relations Sub Group, Planning Promotion Office, CiRA Foundation (CiRA_F)
TEL: (+81) 75-761-3363
Email: PR-g@cira-foundation.or.jp