Research Center for Medical Sciences GMP Production Facilities for Cell Therapy and Gene Therapy

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General Summary

This facility was established for clinical studies based on cell therapy, gene therapy and regenerative medicine. Cell products are generated here on the standard of Good Manufacturing Practice (GMP) for safe administration to the patients in clinical studies. Specified regulation and education have been performed strictly for maintenance of the GMP standard in this facility.

Research Activities

In 2016, a new law, regenerative medicine safety assurance Act, is enforced and all the activities concerning cell therapy including dendritic cell therapy against malignancies must be under the regulation of this law. To continue dendritic cell therapy against glioblastoma multiforme (GBM), that has been performed for more than 10 years in Jikei University Hospital, the procedures for compliance with the new law was required. First, the certified regenerative medical commission (class 3) was established in Jikei University to review the dendritic cell therapy against GBM or other cell therapies. Second, the GMP production facility for cell therapy and gene therapy in Jikei University was inspected by PMDA to be approved as a cell processing center under the new law. Finally, this facility was approved as a certified cell processing center and the dendritic cell therapy against GBM was accepted by Kanto/Shin-etsu division of public welfare in the ministry of health, labour and welfare. Although generation of dendritic cell vaccine using this facility had been stopped during this legal procedure, it started again upon the acceptance. These legal procedures have contributed to the future performance of cell therapy and regenerative medicine under the compliance with the new law in Jikei University.