

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

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Sadamu Homma, *Professor and Director*

Tomoko Ohmae, *Assistant Professor*

### **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**

The two project of cell therapy, dendritic cell vaccine against malignant gliomas and regenerative medicine using nasal epithelial cell sheet in pearl tumor treatment, have been actively performed using this cell processing center (CPC) under the regulation of a new law, regenerative medicine safety assurance Act. No microbial contamination of the cultured cells and the adverse events associated with these cell therapies has been notified. Dendritic cell (DC) vaccine against children's malignant brain tumors is now being planned. As the methods for generation of DC vaccine are same in both adult and child, the same productive space and staffs are available for these studies. However, the productive spaces in this facility are now fully utilized by the on-going clinical studies, no further clinical studies can exploit this facility. Furthermore, considerable cost will be needed for maintenance of the facilities that are being old. New CPC is planned to be built in new Jikei Hospital for out-patients.