

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

---

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 the maintenance of the GMP standard in the facility.

### **Research Activities**

Immune cell therapy, using dendritic cell vaccines against glioblastoma multiforme and pancreatic cancer, and regenerative therapy, using cell sheets from nasal mucosa for tympanoplasty after pearl tumor surgery in the ear, have been successfully performed at this GMP cell-production center. Because a law requiring that the safety of regenerative therapy be assured was enforced on November 25, 2014, our activities of cell therapy or regenerative medicine will be regulated. A working group will establish a committee for third-class regenerative medicine. This GMP cell-processing center must be certificated by the Ministry of Health, Labour and Welfare as a cell-culture facility for regenerative medicine. The devices in this center will be reevaluated by the inspection of the Pharmaceuticals and Medical Devices Agency.