



Manufacturing cell-based therapeutic products for regenerative medicine

Implementing and supporting regenerative medical product manufacturing and quality control

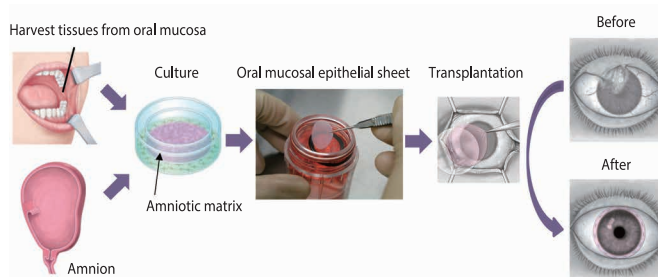
The Division for Regenerative Medical Product Development manufactures regenerative medical products and carries out related quality control for clinical studies. The Division also provides support for associated manufacturing and quality control and carries out R&D for practical application of new regenerative medical products.



Activity

1 Manufacturing a cell-based therapeutic product for corneal regeneration

The cornea on the surface of the eye is covered by the corneal epithelium. When the cornea is degenerated or damaged, the eye surface can become opaque or overlaid, seriously compromising vision. This condition is extremely difficult to treat. Prof. Shigeru Kinoshita, Prof. Chie Sotozono, and their colleagues at the Kyoto Prefectural University of Medicine have developed a cell-based therapeutic product, an epithelial sheet (epithelial sheet developed from oral mucosa) for clinical application. This product is highly effective in repairing the damaged eye surface that is otherwise difficult to treat.



The epithelial sheet is manufactured from cells collected from the patient's oral tissues, which are then cultured on an amniotic membrane as a matrix. Already, epithelial sheets have been transplanted to many patients as part of clinical studies or in advanced medical treatment, demonstrating the safety and efficacy of this technology. To make this treatment accessible in many hospitals, clinical studies are required to enable its commercialization.

The Division has already conducted manufacturing and quality control (inspection) of this product as part of advanced clinical treatment, and plans to continue the same activities for future clinical studies.

Activity

2 Manufacturing a cell-based therapeutic product for cartilage regeneration

Knee joint cartilage has a very limited capacity for self-repair. Once injured, it cannot be repaired or regenerated in most cases. A cell-based therapeutic product for cartilage regeneration has been developed in Germany. Its manufacturing process involves culturing the patient's cartilage cells in collagen gel serving as a scaffold for cell culture. Transplanted, the product is expected to repair damaged cartilage, thus removing the accompanying pain and restoring the functionality of the knee.

In Europe, this product has already been transplanted in many patients for cartilage regeneration. Its safety and efficacy have already been confirmed. Initial clinical study (an investigator-initiated trial) is already done in Japan. To make this treatment technology available in hospitals in Japan, it is imperative that a sponsor-led clinical trial be conducted so that the product can be commercialized within Japan.

The Division has already manufactured this product and conducted its quality control (inspection) within the framework of the investigator-initiated clinical trial. The Division intends to continue the production for the future sponsor-led clinical trial.

