

## [Case Study] Tokyo Medical and Dental University, Medical Hospital



### Blood Infusion and Cell Therapy Center

The compact CPC (Cell Processing Center) is comprised of five preparation rooms for advanced cell therapy and regenerative therapy to fulfill patient re-quirements.

#### As a pioneer that introduced CPC facility

The Blood Infusion and Cell Therapy Center in Tokyo Medical and Dental University, Medical Hospital is working on blood infusion, cell therapy and regenerative therapy in order to support and regenerate dysfunctional tissues and organs.

The university established the Cell Processing Center (CPC) in 2002 for cell therapy and regenerative therapy. The pioneering facility at the time that introduced CPC was established by Professor Tomohiro Morio, a former center chief. The center had three cell preparation rooms and one depressurized room in space of 100m<sup>2</sup> which was designed and constructed by Sanyo Electric, the PHCbi predecessor.

After this, CPCs were required to conform to the structural design standards outlined in the Act to Ensure the Safety of Regenerative Medicine which was established in 2013. With the start of several research and clinical trial projects concerning cell therapy and regenerative therapy within the university, the construction of a new CPC was planned.

The new CPC was designed and constructed by Panasonic Healthcare, also the predecessor of PHCbi that had designed and constructed the previous center, continuing the good relationship from the Sanyo Electric days with excellent support for possible malfunctions that was very highly evaluated.

The new CPC completed in 2014 comprises five cell preparation rooms in the same 100m<sup>2</sup> space, achieving a compact and highly productive work environment. In addition, minimizing cross contamination risk through the definition of movement lines and rooms designed with a chamber pressure difference of 15Pa are also major features.

Currently, in the five cell preparation rooms, there are five projects related to the following research, clinical trials and therapies ongoing at the same time.



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Tokyo Medical and Dental University, Medical Hospital, Blood Infusion and Cell Therapy Center

**Cell Preparation Room 1 (Regenerative Therapy Research Center/Gastrointestinal Department)**

Digestive tract regenerative therapy is being developed here. A small tissue sample is taken from patients suffering from inflammatory bowel disease (ulcerative colitis or Crohn's disease), using an endoscope to increase the stem cells included in the tissue as intestinal epithelial organoid outside the body. After this step, the material is transplanted into a hard-to-treat ulcer using an endoscope again for the treatment.

(Professor Mamoru Watanabe, chief researcher)



**Cell Preparation Room 2 (Blood Infusion & Cell Therapy Center / Blood Infusion Center)**

Unrelated hematopoietic stem cell transplantation through the bone marrow bank and cord blood bank was developed by the Neurology and Pediatric Departments. In order for transplantation to be conducted with minimal risk to patients and donors, research on extracting and preserving cells and post-transplantation complications is conducted to enable clinical applications.

(Michiko Kajiwara, Assistant Center Chief)

**Cell Preparation Room 3 (immune therapeutics)**

Therapeutic vaccine for adult T-cell leukemia (ATL) is developed here. ATL is a poor prognosis malignant tumor caused by the human T-cell leukemia virus type I. It has been found that the cell disorder T cell (CTL) to virus has an anti-tumor effect. Clinical trials of dendritic cell vaccine using tax peptide as antigen are conducted at the identified CTL epitopes site.

(Professor Mari Kannagi, Researcher/Developer)

**Cell Preparation Room 4 (Pediatrics)**

Multiple virus-specific T-cell therapy for treatment-resistant infections is developed here.

Until immunological reconstruction is achieved following a hematopoietic cell transplantation, patients lapse into an immunodeficiency state and tend to become infected by virus-related infections such as adenovirus, BK virus, EB virus, cytomegalovirus, human herpes virus type 6, and others. Since effective treatments are not available and in many cases the infections tend to become severe, clinical trials have started with safer cultures using multiple virus-specific T-cell production within a period of 2 weeks for the five virus types above.

(Professor Tomohiro Morio, Chief Researcher)



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### Cell Preparation Room 5 (Regenerative Therapy Research Center/ Orthopedics)

Physician-led clinical trials are conducted to preserve the meniscus through meniscal repair to the meniscal damage that requires meniscus removal and trans-planting synovium-derived stem cells. In addition, clinical research is conducted to investigate whether knee osteoarthritis deterioration can be controlled by injecting the joint with synovial cells on a regular basis.

(Professor Ichiro Sekiya, Chief Researcher)



## Introducing highly reliable, safe devices to handle the precious cells of patients.

The pharmaceutical refrigerators and biosafety cabinets used in the five cell preparation rooms and ultra-low temperature freezers (-150°C/-80°C) used in the cell refrigeration/preservation rooms and supply rooms are also PHCbi products. These products have an excellent reputation among project personnel as they are easy to use without requiring difficult manuals or complex operation.

Ultra-low temperature freezers employ the “dual cooling system” and incorporate two compressors to eliminate malfunction risk.

“Device malfunctioning can destroy precious cells used in treating patients and compromise research and clinical trial results. The word “sample” may sound somewhat casual, but samples are valuable assets and very important to patients and us. The cell therapy and regenerative therapy we have been working on is a ray of hope to patients. Physicians and researchers are therefore strongly motivated to achieve success in their tasks. They require maximum reliability and safety for the devices they rely on to store cells.

(Professor Ichiro Sekiya, Chief, Regenerative Therapy Research Center)



## Preparing an environment that allows researchers to concentrate on research through the use of monitoring systems and cameras

In order to achieve stable operation of not only a single device but the entire CPC as well, the facility is fully equipped with monitoring systems and surveillance camera systems. Even with careful attention, risk of contamination cannot be entirely eliminated. To minimize risk, the cleanliness, room pressure and temperature in the preparation room as well as the chamber temperature and error status of all devices in the facility connected by cable with the interface board, are monitored 24/7 and work conditions also photographed.

The monitoring system immediately generates an alarm when an abnormality occurs and sends an email to the person in charge. "There had been a case where the CO2 incubator door was not closed completely and allowed the temperature to decrease. I was notified of the error by alarm, and entered the room to securely close the door and so prevented a serious problem." (Person in charge)



An advantage of the monitoring system allows history data to be traced back. If there is a malfunction in a refrigerator, checking the change in chamber temperature from the time the malfunction occurs to when the alarm sounds allows the person in charge to take appropriate post-accident actions for the stored items.

"Thanks to the monitoring system, the person in charge can concentrate on important work without worrying about the cell preparation room and devices."

(Professor Ichiro Sekiya, Chief, Regenerative Therapy Research Center.)

## Continuing to work with precision, dealing with patients on an individual basis and society in good faith

Currently in the center's CPC, each of the five project teams have exclusive use of one cell preparation room for their research. Should the number of cases dealing with cell therapy and regenerative therapy increase, it is expected that other project teams will also want to use the facility so it is necessary to establish a new facility operation method.

"At present, one cell preparation room is used exclusively by one team. However, in the future, there may be a case where one preparation room is used by one team and after cleaning is complete, it is used by another team. What is most important, however, is controlling the cleanliness, room pressure and temperature in the facility to secure the environment required for cell preparation work. In order to achieve this goal, we and PHCbi as a whole want to build a partnership, one that would allow us to work sincerely and with precision, taking the viewpoint of patients and society, not just from the perspective of a customer and manufacturer."

(Ichiro Sekiya, Chief, Regenerative Therapy Research Center)

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Tokyo Medical and Dental University, Medical Hospital, Blood Infusion and Cell Therapy Center

**Products Delivered to :**

Tokyo Medical and Dental University, Medical Hospital  
1-5-45 Yushima, Bunkyo-ku, Tokyo, Japan

<http://www.tmd.ac.jp/medhospital/english/>

**Products Delivered :**

Pharmaceutical refrigerator	MPR-414F-PJ x 6
Medical freezer (-40° C)	MDF-U443-PJ x 1
Ultra-low temperature freezer (-80° C)	MDF-U400VX-PJ x 1
Medical freezer (-150° C)	MDF-C2156VAN-PJ x 1
Laboratory autoclave	MLS-3751-PJ x 4
Biosafety cabinet	MHE-132AJ-PJ x 5
Biosafety cabinet	MHE-130AB3-PJ x 1

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