

CPWS (Cell Processing Work Station) System

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1. Promising regenerative medicine and cell therapy

Regenerative medicine transplanting cultured and propagated human cells in tissues for reproduction and cell therapy represented by cancer immunotherapy came into the spotlight as novel therapeutic methods for treating intractable diseases. Especially, as the use of iPS cells are ethically less controversial and these cells can be easily established from patient's own cells, application and deployment of iPS cells to regenerative medicine and cell therapy are expected.

Cell culture and preservation procedures need to be carried out by ensuring cell safety and quality and it is desirable to comply with GMP (Good Manufacturing Practice). Thus, development of facility and mechanical device/system for supporting GMP compliant cell handlings is one of the important element technologies needed for regenerative medicine and cell therapy to be widely accepted.

2. CPWS system

As one of the methods securing the safety of cell handling procedures such as cell culture and preservation, cell handlings are generally carried out in a cell processing facility called CPC (Cell Processing Center: Cleanroom specialized in handling cells). By creating an aseptic work area in a biological safety cabinet for biohazardous materials while controlling an air flow in a cleanroom, the CPC achieves an aseptic environment for cell handlings.

Although the CPC is used worldwide, it has been difficult to further spread due to its high initial investment (facility building cost: approximately 100 million Japanese yen), large installation space requirement (approximately 100 m²) and high operational cost (approximately 20 million Japanese yen/year). Now, we have first introduced to the world a CPWS (Cell Processing Work Station) system capable of creating an aseptic environment for cell handlings in a space-saving manner by aseptically connecting an isolator achieving an aseptic environment in a chamber through hydrogen peroxide decontamination to a CO₂ incubator required for cell culture, a microscope for cell observation, and a centrifuge. By integrating a process management system for managing cell culture processing information into the CPWS, we can provide a cell culture total system.

Figure 1 shows a structure of the CPWS system. As a glove-box work area takes a sealing structure, an operator, who is the biggest source of contamination, can be isolated. The inner space of the work area is decontaminated with hydrogen peroxide to achieve an aseptic environment. In the work area, a clean level of less than class 100 is maintained by the use of a HEPA filter, and a cell culture module, a centrifuge module and a cell observation module are removably placed. Cell culture tools can be aseptically introduced into the work area or removed from the work area through a pass box capable of decontaminating with hydrogen peroxide. Cell culturing conditions can be visualized using the cell observation module (hydrogen peroxide resistant phase-contrast microscope) for monitoring via a cell observation monitor. In addition, instructions from the process management system can be displayed and checked on the monitor.

The CPWS system is a simple GMP compliant cell processing equipment capable of dramatically saving initial cost, operational cost and installation space. This small device taking its space as little as 2 m² (total installation space: 50 m²) is sufficient to perform simple cell culture procedures aseptically. Therefore, this system does not require elaborated sanitation technique or gowning technique, resulting in dramatically saving operational cost such as aseptic gowning cost (4-5 million Japanese yen/year). Initial cost such as building cost and other operational cost such as an electricity expense can be expected to dramatically

reduce as the facility requires a simple equipment such as a grade D level cleanroom.

3. Sales Performance

In terms of CPC sales, we sold approximately 100 units of CPC mainly in universities in Japan. Based on this performance, we proposed the CPWS system as an alternative cell processing device of CPC to users. As a result, we have sold approximately 70 units of the CPWS system in Japan and 2 units of the CPWS system in the US.

4. Summary

We proposed a CPWS system capable of creating an aseptic environment for cell handlings in a space-saving manner. In the last 10 years since the concept of complying GMP in cell culture environment was introduced, pharmaceutically approved regenerative medicine started and cell therapy such as immunotherapy are emerging.

We plan to further develop and improve device/system to achieve effective and safe cell handlings in order to contribute the wide spread of regenerative medicine and cell therapy.

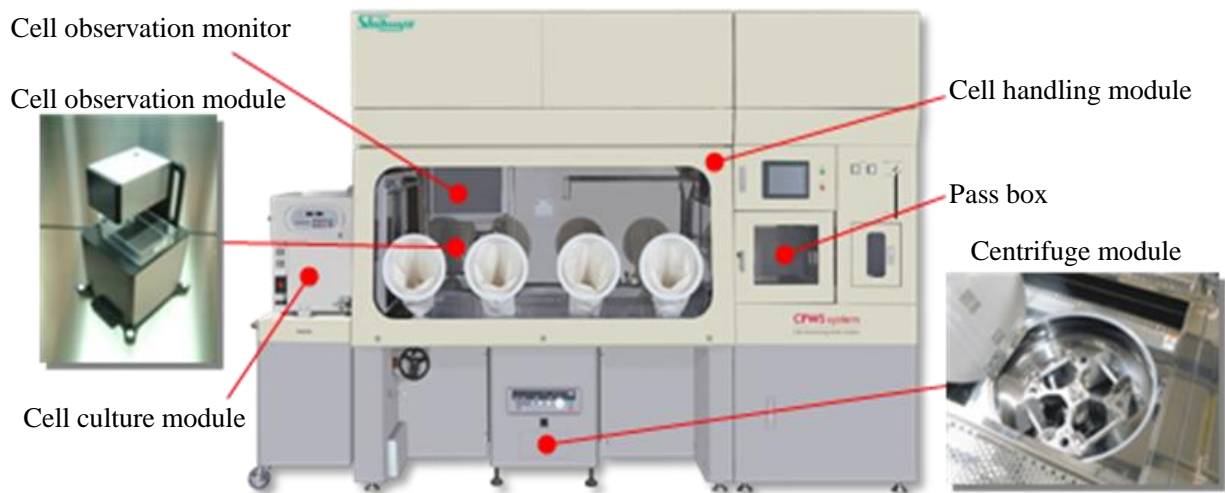


Figure 1 CPWS (Cell Processing Work Station) System