Moving Research Forward

The halls in the Mathews Center for Cellular Therapy (MCCT) are spotless and sprawling. They run along the peripheries of glassed-in workspaces that MCCT director Ann LeFever calls “labs within a box.” Totally insulated from the outside world, the labs circulate sterile air and are equipped with 32 alarms and 100 sensors that erupt should anything disrupt the encapsulated atmosphere.

“Because every aspect of our operation is regulated, we have procedures for everything,” LeFever says. “The products we manufacture are for clinical administration, and this necessitates that the facilities, equipment, personnel, documentation, and processes are all maintained under validated standard operating procedures.”

Welcome to a facility that adheres to good manufacturing practices (GMP). GMPs are federally legislated regulations that are enforced by the United States Food and Drug Administration. They ensure uniformity, consistency, reliability, reproducibility, quality, and integrity. GMPs are set to safeguard the health of patients. This is important because the cellular therapies and other biological products that are manufactured at the MCCT are given directly to patients at Northwestern Memorial Hospital and Lurie Children’s Hospital.

Giving higher doses of chemotherapy to cancer patients might kill more diseased cells, but it also destroys healthy blood cells in the bone marrow. This could lead to life-threatening infections, excessive bleeding, and other serious problems due to low blood cell counts. The MCCT has laboratories dedicated to cellular processing that provide stem cells to patients in order to restore the chemotherapy-damaged immune system.

“Higher doses of chemotherapy can destroy the immune system,” LeFever says. “By transplanting stem cells into the patient, doctors can reconstitute that immune system.”

In addition to aiding patients, the MCCT also supports clinical researchers. For example, Richard Burt, medicine: immunotherapy and autoimmune diseases, uses the expertise of the MCCT to isolate specific hematopoietic stem cells and then transplants these cells to treat Myasthenia gravis, an autoimmune neuromuscular disease. Using stem cell transplantation, Burt’s group eliminates misbehaving immune cells and replaces them with healthy ones, essentially regenerating a new immune system.

Along with the cellular processing labs, the MCCT also has four GMP suites to support research. The facilities offer researchers, clinicians, and biotech companies regulatory compliant labs and services to manufacture highly manipulated and complex biotechnology products. After completing basic research in their labs, researchers can move their project into the MCCT.

“Our labs are clinical grade,” LeFever says. “So therapies and devices developed here can go directly into clinical trials.”

LeFever and her staff provide guidance on developing products, complying to regulations, and certifying products for use. Only one product is allowed in one suite at a time to prevent cross contamination. Researchers can work in a suite with the comfort of knowing that each piece of equipment in the MCCT has been calibrated and tested under rigorous conditions to produce the most accurate and consistent results.
The MCCT’s GMP laboratories have been instrumental for bringing new cellular therapies to Northwestern Memorial Hospital. The preferred treatment option for renal kidney failure is a kidney transplant. Following the transplant, the patient must take immunosuppressive medications for life, and they run the risk of a serious infection or other toxic effects. Doctors need a way to educate the patient’s immune system to accept the donated kidney while still maintaining full immune protection against infection.

**Joseph Leventhal**, transplant surgery, collaborates with LeFever and the GMP facility to solve this problem by combining their scientific and clinical expertise to develop a practical and scalable method for growing regulatory T cells, or “Tregs.” These immune cells have two important qualities: (1) They can be selected to recognize only the cells of the donated organ; and (2) they can then suppress only the immune responses that would otherwise lead to transplant rejection. Up until now, however, it has been difficult to grow enough Tregs to suppress transplant rejection. The MCCT-developed solution is to use its patented immune system modulators and processes to grow Tregs from the recipient to protect the transplant from rejection. Because Tregs can also suppress autoimmunity, this technology can also be applied to treat diseases, such as rheumatoid arthritis, lupus, multiple sclerosis, and other autoimmune diseases.

While the MCCT is located inside Olson Hall on the Chicago campus, it still has users from Evanston. **Guillermo Ameer**, biomedical engineering, will use the GMP labs to develop stents that do not create scar tissue within the body. By coating the stent with a polymer composite, Ameer grows endothelial cells on the tube’s surface. When the stent is implanted into the body, it makes cell-to-cell contact for a seamless connection.

“It is extremely rare to have this type of support at a hospital or university,” LeFever says. “Sometimes, researchers don’t take their products to clinical trials because they don’t have a GMP facility available to them. Others have to travel to GMP labs on the east or west coast.”

The MCCT also serves the other Chicago universities and hospital systems. “We don’t see ourselves as competitors,” LeFever says. “Collaboration is the best way to move health care forward.”

For more information, visit cells.nmh.org.

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**AAAS Seeks Student Aides**

The American Association for the Advancement of Science (AAAS) is currently looking for Student Session Aides for its 2014 Annual Meeting. The meeting is scheduled for February 13-17 in Chicago.

Undergraduate and graduate students can volunteer as aides at sessions of their own choosing—getting to meet and listen to leading scientists, Nobel laureates, popular authors, government leaders, and media personalities. During meeting sessions, aides are asked to count attendees, take notes, and keep track of time.

Student Session Aides receive free registration to AAAS after 8 hours of volunteering and free access to the journal Science online after 16 hours.

To qualify to be a session aide, students must currently be registered in an undergraduate, graduate, or doctoral degree program. Postdocs and professionals are not eligible.

Visit here to apply.