

Cellular Life Solutions, a division of Gulf Coast Regional Blood Center, now has FACT accreditation, marking it as a premier collection center for cellular therapy products. The Foundation for the Accreditation of Cellular Therapy recognizes institutions that demonstrate top-quality care and products in the field of biotechnology. Cellular Life Solutions is honored to have earned this distinction after undergoing a rigorous series of inspections to ensure its products meet the highest standards. The accreditation is the threshold for excellence in cellular therapy and a signal to all that patient needs are paramount to Gulf Coast Regional Blood Center.

Transplant physicians and patients are more confident when products come from a FACT-accredited disease, and international biotech companies seeking quality cellular products rely on FACT standards. In fact, FACT inspectors are considered experts in the cellular therapy field.

## **Benefits of Accreditation**

### **Patient Care**

- FACT accreditation can be achieved across the entire lifecycle of a cellular therapy product or cord blood unit, including collection, processing, storage, and administration.
- FACT Standards for cellular therapy require a robust infrastructure for the full continuum of patient care, from diagnosis and referral, selection of the appropriate cellular therapy product, collection and processing of the cells, preparative regimens, administration of the cellular therapy, post-administrative supportive care, and long-term follow-up and reporting.
- FACT is the only accrediting agency that addresses all quality aspects of cord blood collection, processing, testing, banking, selection, and release.
- FACT Standards guide organizations on necessary processes and procedures to provide quality cellular therapy and cord blood banking.
- Staff at accredited organizations are well trained and equipped to provide excellent services in a culture of quality.
- FACT's emphasis is quality improvement, utilizing expert inspectors and a supportive peer-review process.
- Requirements for multidisciplinary support, chains of identity and custody, and adverse event and occurrence management minimize risks to cellular therapy products and cord blood units and to their intended patients.
- Accredited cellular therapy programs have the robust infrastructure required to administer the right cellular therapy or cord blood unit to the right patient, at the right time, with the right management and supportive care available and implemented.
- Accredited cord blood banks have an inventory that is thoroughly evaluated, stored properly, and reserved correctly to be sure a safe unit is available when a patient needs it.

## Reimbursement and Compliance

- Many health insurance plans and managed care organizations use FACT accreditation as a factor for designating “Centers of Excellence.”
- FACT accreditation is required for patient care reimbursement from some government agencies and health insurance companies.
- FACT Standards are developed by international committees, with input from governmental agencies, to meet or exceed regulations from many regions of the world.

## Shareholder Confidence

- Patients and families seek FACT accredited programs when looking for a quality patient care and treatment program, or when choosing to donate or bank their babies’ cord blood.
- Physicians are more confident in the use of cellular therapy products and cord blood units that meet FACT requirements.
- Pharmaceutical companies seek accredited organizations for the collection of their starting cellular material and administration of their final cellular therapy products.
- Global manufacturers seek consistency among all of their product regions.
- Clients seeking quality cellular products across national boundaries rely on adherence to FACT international standards and accreditation for assurance in proper cell handling.
- Accreditation organizations have obtained the efficiency needed to provide new cellular therapies as they become available in a less burdensome manner.
- US News & World Report utilizes FACT accreditation in its ranking of America's Best Hospitals.

## Opportunities for Participation

- FACT Standards are developed by panels of experts held to the same requirements, and input from accredited organizations and the public is actively sought through periods of open comment.
- FACT accreditation is required of blood and marrow transplant programs that participate in the Cancer Trials Support Unit of the National Cancer Institute, the Children’s Oncology Group, the Eastern Cooperating Oncology Group, and the Southwestern Oncology Group.
- International clients, such as donor registries, require that minimum standards be met for the exchange or use of cellular products, and FACT accreditation is one criterion.
- Standards for health care provider education and training and a robust quality management system equip accredited organizations with the processes needed to expand services as more cellular therapies become available.