

Improving Quality in Cellular Therapy with FACT Accreditation

The Foundation for the Accreditation
of Cellular Therapy

Goals and Services of FACT

- Promote quality patient care and laboratory practice
- Improve treatment outcomes
- Foster continued development of cellular therapies

Pursued through three core services:



Standards



Accreditation



Education

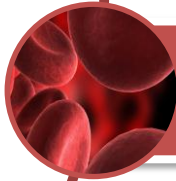
FACT is a Beneficial Accreditation



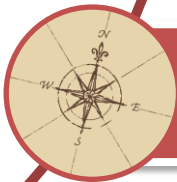
Serves as a resource for patients deciding where to receive healthcare



Used as a criterion by international clients seeking quality cellular therapy products



Demonstrates to clinical trial sponsors that the facility meets requirements published by the experts



Facilitates the establishment of quality management and process control to minimize liabilities

The Global Standard in Cellular Therapy

STANDARDS

Evidenced-Based, International Requirements

- Published medical evidence
 - When not available, requirements are based upon accepted scientific theory and expert consensus
- Written by world-renowned experts in a variety of professional roles
 - Clinicians, scientists, technologists, quality experts, etc.
 - Cell Therapy committee consists of members from 13 countries; Cord Blood committee consists of members from 10 countries
- Public review and comment
 - Public given 90 days to review draft Standards and submit comments
 - Opportunity to provide feedback and participate in the Standards development process

Partnership with JACIE

- JACIE = Joint Accreditation Committee – ISCT and EBMT
 - Established as European accrediting arm
 - “Primary aim is to promote high quality patient care and laboratory performance in haematopoietic stem cell collection, processing and transplantation centres through the development of global standards and an internationally recognised system of accreditation.”
- Develop joint International Standards for Cellular Therapy Product Collection, Processing, and Administration
- Separate accreditation process
- www.jacie.org



Partnership with NetCord

- The mission of the International NetCord Foundation is:
 - To promote the highest quality in cord blood products through worldwide standards and accreditation.
 - To balance global supply and demand for umbilical cord blood.
 - To encourage and facilitate the use of cord blood transplants by promoting laboratory and clinical research and providing professional and public education.
- Develop joint International Standards for Cord Blood Collection, Banking, and Release for Administration
- Joint accreditation process
- www.netcord.org



Elevate Your Position in Cellular Therapy as a FACT Accredited Organization

FACT ACCREDITATION

FACT's Accreditation Program

- Voluntary
 - Cellular therapy programs and cord blood banks *choose* to increase the quality of their processes for the benefit of patients
- Peer-driven
 - Inspectors are your peers who volunteer to serve
 - Inspectors both help and learn from inspections
- International
 - Promotes access to matched donors and quality cell products worldwide
 - Accredited cellular therapy programs in 5 countries and expanding
 - Accredited cord blood banks in 16 countries and expanding

Accredited Organizations



Black = Cellular Therapy Programs; Red = Cord Blood Banks

Why Inspections Are Successful

- FACT staff are dedicated to assisting organizations
 - Accreditation coordinators work directly with organizations
 - Provide Standards interpretation, reminders, tips, etc.
- FACT educational sessions explain requirements and provide examples
 - In-person workshops and online events
- FACT's philosophy is to *help* programs meet minimum requirements
 - Inspectors work professionally in this field and are vested in everyone's success
 - Collegial inspections
- The review process is consistent and objective
 - A global Accreditation Committee reviews every inspection report
 - One person does not decide whether or not a program should be accredited

Areas of FACT Accreditation

- Clinical Program (Transplant Center)
 - Allogeneic, Autologous, or both
 - Adult, Pediatric, or both
- Collection Facility
 - Marrow, Apheresis, or both
- Processing Facility
 - Minimal manipulation, more than minimal manipulation, or both
- Cord Blood Bank
 - Unrelated, related, or both
 - Fixed collection sites, nonfixed collection sites, or both

Preparing for the Accreditation Process

- Review eligibility requirements
- Review the steps to the process at <http://factwebsite.org/accreditationprocess/>
- Complete a self-assessment and address deficiencies
- Attend FACT workshops and webinars
- View FACT tutorials
- Contact the FACT office for assistance
 - fact@unmc.edu, 1-402-559-1950

Educational Offerings



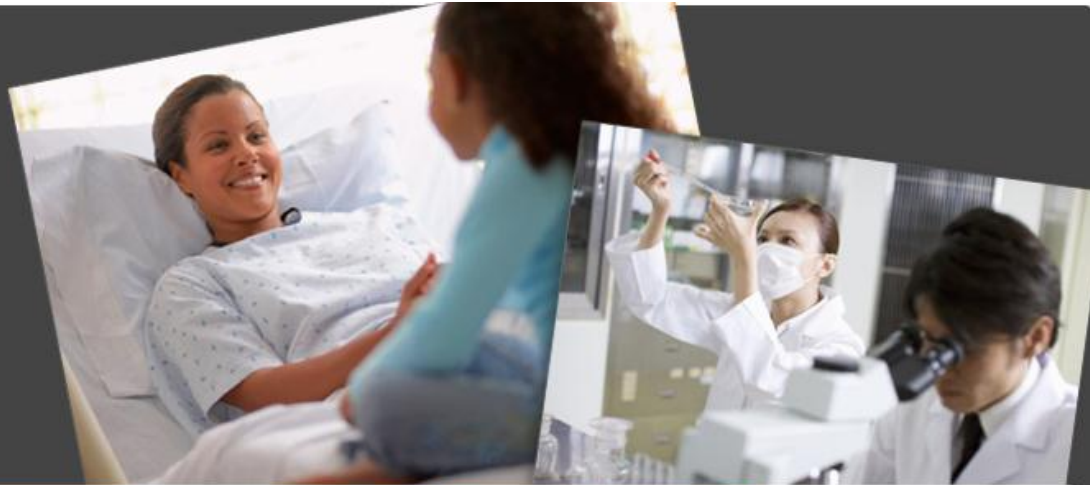
(subscribe by creating a profile at factwebsite.org > FACTWeb > Create a new profile)

Apply for Accreditation

- Create a profile at www.factwebsite.org/factweb
- Submit an Eligibility Application at www.factweb.org
 - Log in with username and password
 - Click “Manage Eligibility Application”
 - Click “Create a New Eligibility Application”

www.factwebsite.org

Setting the
global standard
for top quality
patient care in
cellular therapies



Standards

Accreditation
Process

Become
An Inspector

Education and
Resources

I want to...

Select One



↑
provides details regarding the scope of the Standards and links to regulatory and industry resources.

↑
includes general information pertinent to obtaining initial or renewal accreditation, including accreditation timelines, process overview, and fees.

↑
lists the benefits and expectations of inspectors and provides directions on how to apply to become an inspector.

↑
Lists upcoming educational events and provides links to cellular therapy resources

THANK YOU