



Just the **facts**

Fall 2008 Newsletter

Letter from the President

As an organization, FACT ultimately shares the same goal as the facilities it accredits: continuous improvement leading to a higher quality of care to patients. In the past year we have focused on responding to feedback from the readers of this newsletter - personnel of accredited and applied programs, inspectors, committee members, and other volunteers.

As you read the following pages, feel free to take a little credit for the achievements of FACT. The highlights in this edition are a direct result of the intelligence and collaboration of FACT colleagues.

On behalf of FACT, thanks for all of your contributions to this important and influential organization. Please keep providing your feedback through evaluations, surveys, and messages. They do not go unnoticed and are very important to help us improve.

Hope to see you at ASH,

Fred LeMaistre

Program Relations Committee Survey in the Spotlight

FACT initiated the Program Relations Committee in Spring 2008. The goal of this committee is to strengthen relationships with accredited and applicant programs. A Program Relations Survey was distributed via electronic mail to all programs that have been accredited or inspected.

The survey participation rate was 25 percent, which includes respondents from Clinical Programs, Collection Facilities, Processing Facilities, and Cord Blood Banks. Many of the respondents offered constructive suggestions to improve relations, and appeared to appreciate the survey.

The committee is currently addressing all issues raised by the survey and is happy to report that many of the concerns are already being addressed and implemented by FACT at the present time. A formal, detailed report will be presented to the Board of Directors during the December 2008 meeting and will be published for public viewing in the Winter 2009 edition of the FACT newsletter and on the FACT website.

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Fred LeMaistre, MD

4th Edition Cellular Therapy Standards to be Published November 1, 2008

The FACT-JACIE *International Standards for Cellular Therapy Product Collection, Processing, and Administration* is scheduled for publication on November 1, 2008. These Standards are effective on January 29, 2008.

The FACT Standards Committee, led by Committee Chair Nancy Collins, PhD, began drafting this edition in October 2007. The committee's goal was to further promote quality cellular therapy programs based on new evidence and relevant situations programs currently face. The committee met this goal while achieving the delicate balance between rigorous assurances of quality and practical application of requirements.

The 4th edition Standards will be published on the FACT website on November 1, 2008. Accompanying documentation to be published at the same time include the Accreditation Manual, the Inspection Checklist, the Document Checklist, the crosswalks between the 3rd and 4th editions, and a summary of Significant Changes.



Would you like an assistant or colleague to receive the FACT newsletter?
Anyone can subscribe on the FACT website or by emailing fact@unmc.edu

The Standards promote quality cellular therapy programs and the balance between rigorous assurances of quality and practical application of requirements.

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Passion. Excellence. Progress.

This is the theme of the Bone Marrow Transplant Community's collaborative efforts to be showcased at this year's annual meeting of the American Society of Hematology in San Francisco. The coalition consisting of seven organizations (FACT, NetCord, AABB, ISCT, NMDP, CIBMTR, and ASBMT) has joined forces to help educate and promote careers in cellular transplantation to trainees and fellows. The tremendous growth and progress in transplantation has created a high demand for those interested in pursuing a career in this expanding field.

Visit the FACT Booth (#501) to learn about opportunities in becoming a volunteer inspector, continuing education for current inspectors, accreditation requirements for transplant programs, and highlights of the newly released 4th Edition of FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Transplantation.

Meet the FACT Board of Directors at ASH

Members of FACT's parent organizations, the International Society for Cellular Therapy (ISCT) and the American Society for Blood and Marrow Transplantation (ASBMT), are invited to attend the Annual Meeting of the Members scheduled for 6:00 p.m. on December 5, 2008 in San Francisco at the Westin on Market Street. The FACT Board of Directors will be available to answer questions and provide highlights of FACT's accomplishments throughout 2008 along with scheduled activities for the upcoming year.

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Give us the FACTs Poll

What is your main source of information regarding regulatory and scientific updates?

Give us the FACTs!

Last quarter's poll: Does your program anticipate moving to a new facility in the future?

Response	Percentage
No, we do not anticipate moving to a new facility.	~45%
Yes, within the next year.	~25%
Yes, in one to five years.	~30%

Inspector Area on FACT Website

FACT Inspectors have a new resource center to assist with inspections. The new Inspector Area on the FACT website allows FACT inspectors to initially log in with their email to create a username and password for themselves. Once logged in to the area, the inspectors have access to a variety of training opportunities and tools at no cost.

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FACT Information Technology

Fact is currently exploring new technologies to facilitate the inspection and accreditation process. The new electronic system would make submission of required documentation easier and provide inspectors and applicants their status and information on a real-time basis. Stay tuned for more details!

Online Training: Your Schedule. Your Direction. Your Success.

The FACT online training program began this fall and already has been widely used by inspectors and programs. Tutorials of presentations from the 2008 workshops are available, with more in the process of development. The first webinar, FACT Inspection Exit Interviews, was a resounding success. If you were unable to attend the webinar, you may view the recording of the presentation through the FACT website.

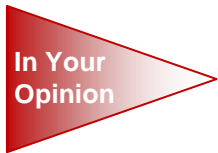
The next webinar, "Professional Inspections: Helpful Tips for a Variety of Situations," will be on November 18, 2008, at 2:00 pm CT. This webinar is only for FACT inspectors, and will be required of all inspectors. If you are an inspector and unable to attend the webinar at the scheduled time, you will be asked to view the recording of the presentation prior to conducting a FACT inspection.

In Your Opinion . . .

What topics would you like addressed during the 2009 cellular therapy and/or cord blood workshops?

Last quarter's survey: Which of the following top ten ways to prepare for a FACT inspection do you feel would help your program the most?

Topic	Relative Frequency
Pay attention to common deficiencies	High
Incorporate Coordinator's feedback	Medium-High
Perform a mock inspection	Very High
Note supporting documentation	Medium
Envision the FACT inspection	Low
Solicit advice from colleagues	Medium
Get to know FACT staff	Low
Visit the FACT website	Low
Attend a FACT workshop	Medium-High
Read the current Standards	Very High



REGISTER TODAY!
Visit the FACT website to register for the upcoming workshops and webinar!

2009 Workshop Schedule:

<p>Cellular Therapy Inspection & Accreditation Workshop</p>	<p>February 10, 2009 in Tampa, FL USA</p>		<p>Tandem BMT Meeting February 11-15, 2009</p>
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<p>Cord Blood Inspection & Accreditation Workshop</p>	<p>March 29, 2009 in Göteborg, Sweden</p>		<p>35th Annual Meeting March 29-April 1, 2009</p>
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<p>Cellular Therapy Inspection & Accreditation Workshop</p>	<p>May 3, 2009 in San Diego, CA USA</p>		<p>15th Annual Meeting May 3-6, 2009</p>
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<p>Cellular Therapy Collection Inspector Workshop</p>	<p>May 19, 2009 in San Diego, CA USA</p>		<p>Annual Meeting May 20-23, 2009</p>
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<p>Cord Blood Inspection & Accreditation Workshop</p>	<p>June 7, 2009 in Los Angeles, CA USA</p>		<p>7th Annual Symposium June 5-6, 2009</p>
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ACCREDITATION REPORT

<p><u>Cellular Therapy</u> 198 Registered 166 Accredited 32 Applications Pending</p>	<p><u>Cord Blood</u> 57 Registered 15 Accredited 42 Applications Pending</p>
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Read the Quarterly Accreditation Report for complete details regarding accreditation activity during the previous quarter.