Letter from the President

FACT has always depended on the contributions of a broad cadre of individuals involved in cellular therapy - physicians, scientists, nurses, technologists, administrators, quality supervisors, and other program personnel - to drive the activities of the organization. Our culture of quality and peer review ensures that the services we provide meet the needs of accredited organizations and advance the collective knowledge of cellular therapy and regenerative medicine. This newsletter reflects the influential impact from our colleagues and experts at FACT accredited organizations.

We are very pleased to provide logistical support to NetCord’s newly announced webinar series – an important educational initiative that will connect cord blood banking experts with bank personnel to present practical aspects of banking cord blood. This training will strengthen the quality of cord blood banks around the world, enabling them to meet the NetCord-FACT Standards and achieve this accreditation sought after by physicians.

The draft fifth edition Cord Blood Standards are currently out for public review and comment. I encourage you to review the draft and submit any feedback you have to the FACT office. Reviewers outside of the Standards Committee provide a fresh perspective and offer additional advice that the committee incorporates into the requirements.

We also are calling for volunteers to serve on FACT committees. FACT has a number of committees that oversee various functions or initiatives and each committee is comprised of individuals from accredited organizations. Each year we greatly appreciate the number of individuals who generously volunteer their time and expertise to serve their colleagues. Often the number of volunteers is greater than the number of open committee positions; however, due to rotating membership and new initiatives, new opportunities may arise. A list of committees is included in this newsletter.

Sincerely,
Helen Heslop, MD

Annual Call for Volunteers

FACT has several committees established to help achieve its vision of being the premier organization setting standards and awarding accreditation to programs in the evolving field of cellular therapy. We invite you to serve the important efforts of these committees. Continued on page 2.

NetCord Announces Cord Blood Banking Webinar Series

NetCord, the international group of leading cord blood banks, is pleased to announce its new webinar series on cord blood banking operations. NetCord recognizes the worldwide need for educational opportunities for cord blood banks. Continued on page 3.
FACT Committee Volunteers Requested
Continued from Page 1

FACT encourages you to review the committees listed below along with their responsibilities and either nominate yourself or a colleague to serve as a committee member. FACT inspectors and others who are active members of one of FACT’s parent organizations, ASBMT and ISCT, will be considered for committee membership.

**Individuals with cord blood banking experience are especially requested to enhance current committee membership.** Committee chairs will notify final candidates of their appointments.

Due to overwhelming responses from dedicated individuals, FACT cannot always place everyone on a committee. Even if you expressed interest in a committee in the past but were not placed, please express interest again. FACT rotates membership to incorporate a variety of perspectives and ideas into committee activities. Please indicate which of the committee(s) you would be interested in serving as a member via the [online committee volunteer form](#) by December 7, 2012.

**Accreditation Committee**
Review on-site inspection reports in a timely, fair, and consistent manner to make recommendations to the FACT Board of Directors regarding applicant program accreditation status.

**Education Committee**
Develop training programs for applicants to ensure knowledge and understanding of current standards and provide tools for preparing for inspection. Enhance the inspector training program to incorporate continuous quality improvement and ensure the participation of all inspectors.

**Standards Committee**
Develop core standards and associated guidance materials. Although publication is every three years, the standards development process is ongoing. Address the need for interval or emergency standards. Develop an ongoing dialogue with other cellular/gene therapy organizations to move toward joint standards and accreditation.

**Professional Relations Committee**
Develop a primary objective for relations with each of the following organizations and agencies: ISCT, ASBMT, NetCord, ASFA, NMDP, AABB, CAP, ASHI, and ASGCT.

**Quality Management Committee**
Provide educational programs and tools on quality management. Systematically audit FACT inspections to ensure continuity. Monitor developments in treatment outcomes evaluation and reporting.

**Public Relations and Marketing Committee**
Enhance visibility of FACT throughout the stem cell transplant community and the cord blood banking industry. Educate constituency about benefits of FACT accreditation including FDA preparedness.

**Program Relations Committee**
Enhance communications with accredited organizations to assess needs and provide timely information and additional services. Survey centers to identify needs of accredited transplant facilities and cord blood banks.

**FACTWeb Oversight Committee**
Enhance accreditation process and communications through the maintenance of the FACTWeb system. Evaluate the needs of all users including inspectors, programs, committees, and staff.

**Joseph Schwartz, MD Named Sixth Edition Standards Chair**

The FACT Board of Directors announces that Joseph Schwartz, MD has been nominated as the Sixth Edition Standards Committee Chair. Dr. Schwartz is the Director of Transfusion Medicine at the New York Presbyterian Hospital/Columbia University Medical Center Blood and Marrow Transplant Program. His professional responsibilities provide him with a well-rounded perspective in cellular therapy extending from transplant medicine to directing collection and processing of cellular therapy products. He is active in cellular therapy societies, including his membership on the Board of Directors of the American Society for Apheresis and the US ISBT 128 Consensus Standard Committee for Cellular Therapy Products.
NetCord Webinars to Address Day to Day Cord Blood Banking Operations

Continued from Page 1

The quarterly webinars will feature leaders in cord blood banking and present information related to specific banking operations. As cord blood increasingly becomes a source of cells for hematopoietic progenitor cell (HPC) transplants and research studies, the quality of the cord blood banks’ processes has a greater impact on the cellular therapy field and patients. Furthermore, the number of cord blood banks around the world is increasing.

The goals of these webinars are to:

• Provide new and upcoming cord blood banks basic information about effective day-to-day operations.
• Enhance the knowledge of established cord blood banks on current issues regarding cord blood transplantation and research.
• Encourage cord blood banks to achieve FACT-NetCord accreditation, the global standard in cord blood banking sought after by physicians and patients.

The NetCord webinars are offered as a benefit to its member banks at no cost. FACT inspectors can also register for the webinars free of charge. All other cord blood bank personnel will be assessed a nominal fee. Registration for the sessions is powered by FACTWeb. Registration is open for the 2013 webinar series:

**Cord Blood CD34 and Cell Content:** January 31, 2013 at 1400 GMT
Riccardo Saccardi, MD, of Careggi University Hospital Cord Blood Bank in Florence, Italy will discuss a prospective study on behalf of Eurocord and NetCord on Cord Blood CD34.

**Measuring Viability of Cord Blood Products:** April 25, 2013 at 1300 GMT
Presenters include Sergio Querol Giner, MD, PhD of Programa Concordia Banc de Sang i Teixits and Richard Duggleby, PhD of the Anthony Nolan Research Institute. Cell dose is an important parameter in predicting a good outcome in cord blood transplantation, particularly the extent of functional progenitor cells infused. This webinar will address the various methods for progenitor cell assessment that have been used and their applicability in the CB field.

**Cord Blood Cryopreservation:** July 25, 2013 at 1300 GMT
Paolo Rubella, MD of the Center of Cellular Therapy and Cryobiology at the Fondazione Ca’ Granda Ospedale Maggiore Policlinico, Milan, Italy will present basic concepts in cryobiology related to ice formation in biological materials during transition from liquid to frozen phase. Examples will be given of “good” and “bad” cord blood cryopreservation thermal profiles.

**Cord Blood Potency and Release:** October 10, 2013 at 1300 GMT
Gesine Kögler, PhD of the José Carreras Cord Blood Bank will present this webinar on potency and release. Cord blood units are not only intensively examined during processing before cryopreservation, but also prior to release for transplantation. Therefore, potency of a unit must be defined before release on segments and cryopreserved aliquots. Methodological aspects and technical improvements will be discussed.
Interim Standards and Accreditation Manual Updates Published

FACT and JACIE have published interim standards and updated guidance in the fifth edition *FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing, and Administration*. These changes were incorporated into the fifth edition in response to feedback received from transplant programs and organizations. Changes to a current edition of Standards are reserved for only those that are urgent in nature or frequently requested with compelling reasons. Because the interim changes relaxed a requirement, clarified regulatory requirements, or reinforced the original intent, no public comment period was opened. The interim standards will be effective after 30 days, or November 30, 2012. The changes made are summarized in Appendix IV of version 5.2 of the Standards and Cellular Therapy Accreditation Manual. (Version 5.1 did not include the red cell antibody screening changes to CM6.3.10 and C6.4.2.)

**Interim Standards**

B6.4.2, CM6.3.10, C6.4.2: A red cell antibody screen shall be performed on allogeneic donors and allogeneic recipients.

B4.10.5: Deviations from the following key Standard Operating Procedures, B5.1.1, B5.1.65, and B5.1.76, shall be documented. (for clarity)

D6.1.7: Cellular therapy products that do not meet release or allogeneic donor eligibility requirements shall be distributed only if there is documented urgent medical need for the product. Documentation shall include, at a minimum, the approval of the recipient’s physician and the Processing Facility Medical Director or other designated physician.

D6.1.7.1: Notification of the transplant physician of nonconforming cellular therapy products and approval for their release shall be documented. (for clarity)

B3.4.3.3: Pre-transplant patient evaluation, including assessment of appropriate patient eligibility-suitability and HPC adequacy with respect to collection. (for clarity)

**Accreditation Manual Updates**

FACT, in partnership with JACIE and NetCord, updates the Cellular Therapy and Cord Blood Accreditation Manuals to proactively share precedent-setting decisions with inspectors, programs, and banks so that everyone is able to accurately apply the Standards in the same manner as the Accreditation Committees. This information helps the intent of the Standards to be consistently applied by all programs and banks and subsequently assessed by inspectors. The changes made are summarized in Appendix IV of the updated Accreditation Manuals.

Both the Cellular Therapy and Cord Blood Accreditation Manuals have been updated to explain the different areas of ASHI accreditation (Cellular Therapy Standard B2.4.6 and Cord Blood Standard B4.7). In addition, the Cellular Therapy Accreditation Manual has additional information regarding the following:

- Access to Marrow Collection Facilities and physicians trained and competent in marrow collection (B3.3.4)
- HLA typing (B6.4.10)
- Safe administration of preparative regimens (B7.4)
- Representative samples (D6.1.2.2)
- Throughout the manual, clarification that donor eligibility refers to only allogeneic donor eligibility for consistency with FDA requirements and the FACT-JACIE Standards.
New Electronic Record Requirements Clarify Scope of FACT Inspections

With the rapidly increasing use of electronic record systems at accredited organizations, the Standards Committee clarified which of these systems are within the scope of FACT inspections. Cellular Therapy (CT) Standards C11.6.1 and D12.2.1 and draft fifth edition (CB) Cord Blood Standard B11.8.1 outline how to decide if an electronic record system must meet the FACT Standards:

• Is it the control of the facility? Many enterprise systems, such as patient medical records, are typically inspected by other regulatory and accrediting organizations. Such systems are dictated by institutional leadership and programs and banks are required to use them. Because Directors have little authority over them, and because their validation, implementation, and maintenance are directed by other departments, programs and banks are only able to exert minimal influence.

Once a system is determined to be in control of the facility, the following criteria apply:

• Is the electronic record used in lieu of paper? If the electronic record is the official data repository and source of information, then it is used in lieu of paper and in the scope of the FACT inspection. An example of a system that is not used in lieu of paper is one that generates a report that is printed and added to the product record, which is considered the official record.

• Is the electronic record used to make decisions based upon data stored and/or created by the electronic record system? If data in the electronic system is used to make decisions such as whether or not a product meets release criteria or to perform outcome analysis, it is considered critical. Using the example system above, if the data that is entered in the system is used to conduct outcome analysis rather than using the official paper record, then the system must meet the Standards.

• Is the electronic record used to make calculations via automated functions? Processing worksheets are often created electronically either in complex computer software or simple Excel spreadsheets. When the worksheets are built to make automated calculations, the system must meet the FACT Standards.

FACT and NetCord will continue to accept comments on the draft fifth edition International Standards for Cord Blood Collection, Banking, and Release through December 6, 2012. Please review the Request for Public Review and Comment for a description of the documents available for review and instructions for submitting comments.

The final Standards will be published on July 1, 2013 and will become effective on September 29, 2013.

Don’t Forget to Submit Your Comments on the Draft Fifth Edition Cord Blood Standards!

FACT and NetCord will continue to accept comments on the draft fifth edition International Standards for Cord Blood Collection, Banking, and Release through December 6, 2012. Please review the Request for Public Review and Comment for a description of the documents available for review and instructions for submitting comments.

The final Standards will be published on July 1, 2013 and will become effective on September 29, 2013.
First Cellular Therapy Program in Asia Achieves Accreditation

The National University Hospital Haematopoietic Progenitor Cell Transplant Program in Singapore, directed by Dr. Tan, is the first program to achieve FACT accreditation in Asia. The availability of high-quality matched cellular therapy products for patients depends on international consensus and collaboration, and this accreditation demonstrates the impact accredited organizations have on the availability of lifesaving cells for people in need around the world. Congratulations to Dr. Tan and his program on this accomplishment!

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FACT has conducted several inspections using the FACTWeb accreditation portal. The following are important updates and tips.

The recommended browsers for use with the FACTWeb accreditation portal are Chrome, Mozilla Firefox and Safari (for Apple products). Internet Explorer 6 and above will also work. FACTWeb has been tested to work on PC and Apple desktops and laptops and the iPad. Individuals that have experienced FACTWeb with other devices are encouraged to submit their feedback to askfact@unmc.edu. FACT requires applicants to offer internet connection for FACT inspectors during the onsite inspection by offering a wired connection, a WIFI connection, or a computer with internet connection.

Online FACTWeb demonstrations have been conducted with all inspection teams prior to scheduled onsite inspections. Starting in January 2013, the demos will be scheduled once a month and inspectors scheduled for an inspection will be asked to register for an upcoming demo. The application submission and the inspection report submission have deadlines marked in red on the application. As soon as the deadlines pass, the application and reports can no longer be submitted to FACT until the FACT Accreditation Coordinator is notified and modifies the deadline.

In the Compliance Application, FACT included special tips for many standards. These are displayed with an 🔄. To view the tip, hover your cursor over the symbol.

**Dennis Gastineau, MD Shares His FACTWeb Experience**

Dennis Gastineau, MD, Vice-President of the FACT Board of Directors and Chair of the FACT Education Committee, recently performed a FACT inspection using the new online FACTWeb accreditation portal. He shares his experience to help other inspectors prepare for using the new system.

Before the inspector, he and his inspection team viewed an online demonstration of FACTWeb. This session lasted about 45 minutes and he felt reasonably comfortable with the system after that. Other educational sessions (such as webinar recordings and the FACTWeb Inspector Guide) provide necessary background information.

Dr. Gastineau found that the structure of web-based documentation makes it much easier to associate the documents with the particular standard. Immediate access to the Standards and guidance information was one of the biggest differences between the paper-based inspection process and the electronic process. The other big difference was the time it took to complete the inspection report. Dr. Gastineau’s report was almost completed upon leaving the program. Beyond that, he spent less than 15 minutes putting together the rest of the report. He estimates the effort to write the inspection report decreased by 85 percent.

Dr. Gastineau primarily entered notes directly into the system except when touring the facilities, which makes it more difficult to type into the system. Another inspector made handwritten notes and then entered them into the system after the inspection. At one point, he did become confused about what type of note he was entering. Inspectors may write two kinds of notes: Review Notes, which are general observations or reminders to themselves or to applicants, and Inspection Notes, which are citations or suggestions that are automatically included in the inspection report. He also found that having two screens active helps. He brought his laptop and his iPad and this reduced the need to toggle back and forth.

He recommends that inspectors use the electronic checklist throughout the day because it makes it easier to complete the report and allows immediate access to guidance information. Reviewing the answers to each of the compliance questions and entering notes in the system prior to arriving on site will minimize the need to take manual notes throughout the inspection day.

As Education Chair, Dr. Gastineau acknowledges that it is natural to be nervous about using the system for the first time. He assures everyone that his first experience was very good – response times were quick and the electronic web-based system did not add time to the inspection day.
Quality Corner: Planning for Major and Minor Disasters

Jill Hempel, MS, ASQ-CMQ/OE, CQA

As Hurricane Sandy gives us all a frightening reminder of how disasters can affect our daily lives, Clinical Programs should review its plans for major disasters and emergencies so that recipients, donors, and cellular therapy products are not adversely affected. The fifth edition of the Cellular Therapy Standards requires programs and facilities to address disasters and emergencies in its SOPs (See B5.1.10, C5.1.17, and D5.1.22). Institutional policies for general responses can be used, but specific procedures relating to the chain of command and necessary procedures to address the programs’ and facilities’ responses are needed to augment the institutional guidelines. For example, the safety of stored stem cell units and immunocompromised patients are unique issues not likely addressed in hospital-wide plans. The article Preparing for the Unthinkable: Emergency Preparedness for the Hematopoietic Cell Transplant Program (Wingard et al, 2006) provides a framework for disaster plans that can be customized for individual Clinical Programs.

In addition to requirements for disaster plans, new standards implemented in the fifth edition require that quality management plans include policies and procedures for actions to take in the event operations are interrupted, but do not rise to the disaster level (e.g., power outage, drug shortages, equipment failures, etc.) The program does not need to outline every specific event that may occur but describe actions to take when there is an interruption of operations, including who needs to be contacted, how to prioritize cases, and key personnel to be involved in identifying alternative steps to continue functions (See B4.12, C4.12, and D4.12 and accompanying guidance). The FDA provides helpful information concerning the storage of temperature-sensitive biological products that can be affected both by disasters and interruption of operations in its article Impact of Severe Weather Conditions on Biological Products.

FACT sends its condolences and well wishes to the regions affected by Hurricane Sandy and thank the institutions that are caring for its victims. Such events demonstrate the importance of planning for disasters in advance and the reassurance those plans provide in times of crises.

Coordinator Commentary - Tips for Completing RFIs

Sarah Litel-Smith, BSMT(ASCP)

As more programs use the FACTWeb accreditation portal, it is important to note that the FACT Accreditation Coordinators are available to assist programs in using the system. One of the most common tools we use for communicating with programs through the system are Requests for Information (RFIs). RFIs allow the program to expand, clarify, or provide additional documentation. RFIs can be generated throughout the entire accreditation process from the initial application through the post-inspection response. The “Reviewer Notes” contains the request.

The most common issue programs currently are having with submitting their response to RFIs is completing the submission. For each RFI generated, the program needs to enter a response in the comment section or upload the applicable document. The next step is the most frequent cause of problems with completing the RFI: Once an RFI is complete, the program must uncheck the “Not Complete” box right under the standard and then click the “Save” button. If the “Not Complete” box is still checked, the system will never consider the RFI complete no matter what has been uploaded.

Another issue that may prevent the program from completing the RFI is that the due date has passed. When the RFI is generated, a due date is set. The due date is contained in the e-mail notification sent to the program. The due date may also be verified by logging into the Compliance Application through the FACTWeb accreditation portal. If the due date has passed, the solution to this issue and any other issue you may be having is a phone call to your FACT Accreditation Coordinator for assistance.
**Alliance for Regenerative Medicine Publishes the Why, What, When and How of Communication with the FDA**

The Alliance for Regenerative Medicine (ARM), multi-stakeholder advocacy organization that promotes legislative, regulatory and reimbursement initiatives necessary to facilitate access to advances in regenerative medicine, published *Communications with the Food and Drug Administration on the Development Pathway for a Cell-Based Therapy: Why, What, When, and How?* (Feigal, et al., October 17, 2012) in Stem Cells Translational Medicine.

This paper explains how to maximize the productivity of dialogue with the FDA and develop an effective regulatory strategy for cell-based therapies, which pose unique challenges to demonstrating safety and effectiveness. An overview of the types of interactions with the FDA that are available is provided while also noting common pitfalls to avoid.

**ASBMT Guidelines for Training in HPC Transplantation**

A primary objective of one of FACT’s parent organizations, the American Society for Blood and Marrow Transplantation (ASBMT), is to ensure the highest quality of medical practice for patients undergoing hematopoietic progenitor cell transplants (HCT). The progressive complexity of HCT transplants and the growing demand for transplant physicians prompted the formation of the ASBMT Committee on Education. The committee published updated training guidelines, *American Society of Blood and Marrow Transplantation Guidelines for Training in Hematopoietic Progenitor Cell Transplantation* (Khan et al, 2012), which provide an extensive and detailed framework. The guidelines are aligned with the six areas of Core Competencies defined by the Accreditation Committee on Graduate Medical Education (ACGME).

Physician training and competency, and subsequent documentation, is often a source of ambiguity for FACT-accredited clinical programs. In addition to providing specific content for a HCT physician training program, the guidelines provide example methods to determine the trainee’s progress and ultimate competency.

**College of American Pathologists (CAP) Offers Cord Blood and Stem Cell Processing Surveys**

Processing Facilities and Cord Blood Banks seeking proficiency testing for laboratory assays can enroll in the CAP Cord Blood and Stem Cell Processing Surveys (Codes CBT and SCP respectively). Procedures such as Absolute CD34, Bacterial Culture, Colony Forming Units (CFU), and Viability are included among others. For further details, see the [CAP 2013 Surveys Catalog](#).

**Join ISCT Today!**

Gain access to an influential global community of peers, experts, and organizations invested in cellular therapy. With its origins in laboratory technology, the [International Society for Cellular Therapy (ISCT)](http://www.isct.org) continues to set quality and operations standards in cell therapy. ISCT brings together key opinion leaders, government regulators, commercial partners and cell therapy technologists, and offers a unique collaboration between academia, regulatory bodies and industry in cell therapy translation.

ISCT members also enjoy:
- A subscription to ISCT’s official journal - *Cytotherapy* - as well as a subscription to ISCT’s bi-monthly member e-newsletter - *Telegraft*.
- Discounted rates to ISCT-sponsored events, including webinars, regional meetings, and the ISCT Annual Meeting.
- Access to ISCT’s three pillars of value (Academia, Regulatory, and Commercialization) through the newly upgraded, highly searchable member networking database, and participation in stakeholder committees.
- Free downloads from the ISCT webinar library, access to past meeting presentations and more!
- Technologist-specific information from the ISCT Laboratory Practices Committee and laboratory resources library.
BMT Administrators Requested to Complete Survey for FACT Presentation at the 2013 BMT Administrators Conference

FACT will present Practices for Complying with FACT Standards and Navigating New Editions at the 2013 BMT Administrators Conference on Friday, February 15, 2013 in Salt Lake City at the BMT Tandem Meetings. This presentation will provide tips for transitioning to new editions of Standards and share ways programs are complying with difficult requirements. To make this presentation as useful to BMT Center Administrators as possible, FACT is requesting BMT Administrators to provide suggestions about potential topics. Please share new or existing fifth edition Standards that your program would like more information on via our BMT Administrators Poll. We appreciate your input and hope to see you in Salt Lake City!

OCTGT Learn Enhances Understanding of FDA Requirements

OCTGT Learn, the Center for Biologics, Evaluation and Research’s (CBER) Office of Cellular, Tissue and Gene Therapies (OCTGT) web page for industry education, provides several educational courses that enhance understanding of FDA requirements. Currently offered courses include:

- **IND Basics in OCTGT**: Presenter: Patrick Riggins. This presentation looks at the basics of IND submission in OCTGT.
- **IND Safety Reporting (New)**: Bindu George provides basic information regarding the FDA safety reporting requirements for INDs.
- **Early-Phase Trials of Cellular and Gene Therapies (New)**: Steve Winitsky discusses the clinical risks of cellular and gene therapy products, and reviews some considerations for the design of early-phase trials of these products.
- **Regulatory Obligations for Investigator-Sponsored Research (New)**: Pat Holobaugh discusses the regulatory requirements for an investigator who is also a sponsor of an IND or IDE.
- **Pediatric Clinical Trials (New)**: Steve Winitsky discusses the regulation and design of pediatric clinical trials.

Additional courses are online, and more may be developed and posted upon completion. You may submit suggestions for future courses to OCTGTLearn@fda.hhs.gov.

Attention Mentors!

Inspectors who willingly serve as mentors to trainee inspectors during their training inspection serve a valuable role in this critical step in education and practice. Mentors must be available and supportive to trainees before, during, and after the entire inspection process. Provide your advice on how to prepare for the inspection, assist with standards interpretation, and review and follow-up on the trainee’s inspection report. Thank you for preparing the next generation of FACT inspectors to conduct the collegial, objective, thorough, and consistent inspections FACT’s reputation is founded upon.
2013 Workshops Open for Registration
The 2013 FACT workshop agendas address commonly misunderstood requirements and exciting developments in cellular therapy and cord blood banking. The following workshops are open for registration!

**Cellular Therapy Inspection and Accreditation Workshop**
*Salt Lake City on February 12, 2013*
*In conjunction with the BMT Tandem Meetings*

**Agenda**

The Clinical Program Track will discuss information specific to Clinical Programs. The Introduction to Cellular Therapy Inspections Track provides an overview of information related to the inspection of the entire cellular therapy program including clinical, collection, processing, and quality management functions.

**Registration**

Sessions for both Cellular Therapy Programs and Cord Blood Banks will be available! The Cellular Therapy Track includes guest presenters from the Baylor College of Medicine to discuss exceptional release and product recalls and from the Clinical Cell and Vaccine Production Facility and Immunologic Monitoring and Cellular Therapy Products Laboratory to discuss pursuing FACT accreditation to improve the quality of research products. The Cord Blood Track includes guest presenters from the Children's Hospital at Westmead BMT Service to discuss post-thaw data and the BMDI Cord Blood Bank to discuss cord blood research and its impact on banks.

**Cellular Therapy Collection Workshop**
*Denver on May 22, 2013*
*In conjunction with the ASFA Annual Meeting*

**Agenda**

This workshop will once again be a full day - allowing time to discuss a variety of collection-related issues, including trending incidents and adverse events, communicating with clinical programs and processing facilities, and extracorporeal photopheresis.

**Cord Blood Inspection and Accreditation Workshop**
*San Francisco, CA on June 9, 2013*
*In conjunction with the International Cord Blood Symposium*

**Registration**

Stay tuned for the agenda!

**Suggest Educational Topics for the 2013 Online Calendar**

The Education Committee is welcoming suggestions for educational topics to include in online training in the coming year. Please submit ideas that you and your colleagues would find helpful to fact@unmc.edu. The committee would also appreciate volunteer presenters – if you have a topic you are willing to present, please submit it along with your curriculum vitae or resume.