

FACT Update, June 2021

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FACT Virtual Workshop and Quality Boot Camp Were a Success!

FACT held its third virtual workshop on May 6th and second virtual boot camp on May 21st. Though the pandemic prevented the conference from taking place in New Orleans, it could not stop the cellular therapy community from gathering together to continue to advance their programs via e-learning. Over 200 individuals joined each of the live events!

Countries Represented (Workshop Registrants), N=251





We send a huge thank you to our workshop chairs, Dr. Nicole Aqui, Dr. Leon Su, Sara Murray, BSc, DAS, and Brian Jones, SBB (ASCP); our quality boot camp chairs, Ed Brindle, MSc, MLT and Leigh Gates, CPHQ; the FACT Education and Quality Management committees; our fabulous presenters and facilitators; and, of course, our attendees for their abundance of energy and enthusiasm.

FACT Inspection & Accreditation Virtual Workshop – May 6, 2021

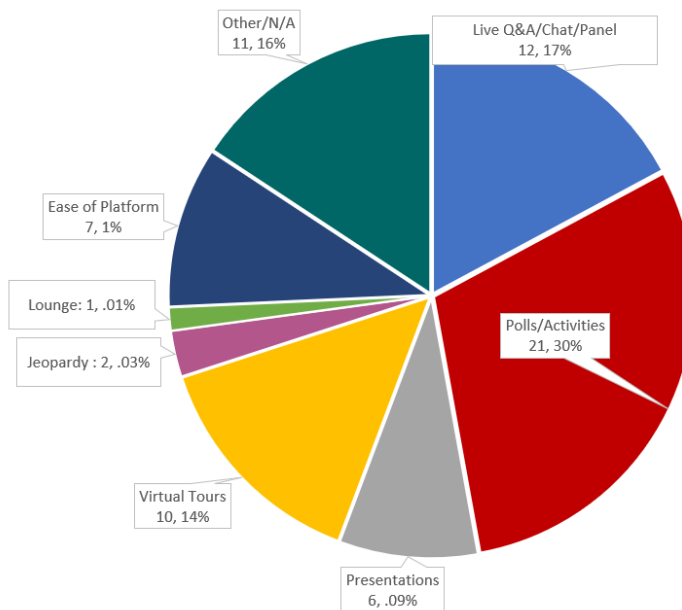
The workshop morning was split into an apheresis track and a processing track. Both tracks included the following sessions:

- An overview of FACT Accreditation
- A review of the compliance application process
- How to prepare for an inspection
- A virtual tour of an accredited apheresis program and processing facility
- Common challenges apheresis and processing programs encounter & how to correct the deficiencies

The afternoon presented more advanced content for attendees that had previously attended a workshop and were more familiar with FACT Accreditation. The sessions included:

- How to prepare for a FACT virtual inspection
- Navigating the Eighth Edition for Cellular Therapy Standards
- How Chain of Identity and Chain of Custody Can Help
- A panel discussion with all workshop presenters

What were your **favorite features** in the virtual event platform? (N = 70)



FACT Quality Boot Camp in Partnership with ASFA and ISCT– May 21, 2021

The quality boot camp explored core quality concepts throughout the day and participants learned how to apply those concepts during interactive sessions focused on apheresis or processing. The sessions included:

- An overview of the change control process and its development for new or changing services
- Translating Risk Assessment into Practice (Developing & Use of a Risk Assessment Tool)
- Getting the Train Moving Successfully with Process Validations
- Using Audit Findings to Improve Your Program: Root Cause & CAPA
- Unexpected Outcomes & Events: Chain of Custody and Chain of Identity
- Interactive discussions to reinforce the concepts of change control, risk assessment, validation, and audits

What Were Your Favorite Experiences or Moments of the Event?



**Networking with
Colleagues**

"I really appreciated the case studies/real life examples that almost all of the presenters shared to further illustrate points in their presentations. Very helpful."



Jeopardy

"I learned a lot from my group members during the breakout activities. Many in my group were from processing labs of a similar size to mine, which was great! We were able to compare and contrast our various practices in a way that would not be possible with very small labs."



**Interactive
Sessions**



Q&A

"My favorite moment was understanding how each quality topic is intertwined with each other. That is, event management, change control and CAPA can be used together to improve processes. Risk management can be used throughout all quality processes, such as validation, change control, event management and CAPA."



**Presentations/
Speakers**

"To find so many people offering help and advice!"

Both the workshop and the quality boot camp included optional sessions at lunch. The first session featured Jeannette Bloom from Baylor College of Medicine Stem Cell Transplant Program. FACT inspector Dr. Tom Leemhuis talked with Jeannette about her experience as one of FACT's first virtual inspection programs. Attendees were able to hear what worked well, what challenges the program faced, and suggestions for moving forward. The second session was a speech from incoming FACT President, Catherine Bollard, about her vision for FACT as we move forward. Jeopardy was a popular segment in both conferences as participants enjoyed reinforcing concepts discussed throughout the day in a fun and interactive method.

Register for the FACT Webinar: Navigating the Eighth Edition FACT-JACIE Cellular Therapy Standards



Navigating the Eighth Edition FACT-JACIE Cellular Therapy Standards

SPEAKER



Dr. Paul Eldridge
Levine Cancer Institute

The Eighth Edition of the FACT-JACIE Hematopoietic Cellular Therapy Standards was published on May 17, 2021 and will be effective on August 16, 2021. To support FACT accredited and applied programs during this transition, FACT is offering a webinar on how to navigate the Eighth Edition Cellular Therapy Standards. Dr. Paul Eldridge from Levine Cancer Institute, the Standards Committee Chair, will explain changes including:

- Genetically-modified cellular therapy products
 - Training in GXP
- Quality management
- Informed consent
 - Labeling
 - Storage

21 JULY 2021 | 11:00 AM ET, 15:00 GMT

REGISTER NOW

www.factwebsite.com

**Register for the
Webinar!**



Happy 25th Anniversary to the FACT Community!

Join FACT in celebrating 25 years of working together to improve the fields of cellular therapy, cord blood banking, and regenerative medicine. Congratulations to all FACT's volunteer inspectors, committee members, leadership, accredited organizations, staff, and supporters for making this milestone possible.

We invite readers to sign our [25th Anniversary Guest Book](#) and leave a greeting, photo, or video. Additional celebratory events and activities will take place throughout the year.