Beyond transplantation: Creating standardization across the cell and gene therapy industry

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Be The Match BioTherapies®
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The following faculty and planning committee staff have the following financial disclosures:

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Learning objectives

• Identify two or more ways to prepare their institution for requirements of cell and gene therapy activities

• Access Be The Match BioTherapies support resources available when implementing new protocols or cell and gene therapy requirements

• Describe how to participate in developing standards for cell and gene therapy
Our panelists

Amy Hines
Director, Collection Network Management
Be The Match BioTherapies

Heather Steinmetz
Quality Assurance Manager
UCLA Health

Hope Guidry-Groves
Director, Cellular, Apheresis and Transfusion Services
Gulf Coast Regional Blood Center

Dawn Henke
Senior Technical Program Manager
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Ann Kemp
Senior Manager, Regulatory Compliance
Be The Match BioTherapies

Grab your cape.
History of hematopoietic cell transplantation

Annual Number of HCT Recipients in the US by Transplant Type


Grab your cape.
Cell and gene therapy clinical trials and commercialized protocols

- Immunotherapy
- CAR-T
- TIL
- NK
- Gene Therapy
- TAC-T

Grab your cape.
Managing a **global cell therapy supply chain**

- 30 years of expertise and global leadership
- 86,000 total stem cell transplants managed
- 112 contracted apheresis and collection centers
- 22,000 cell and blood shipments annually
- 6,000 annual stem cell transplants
- 19 million donors on the world’s largest registry
- 220 research studies underway
- 900 employees strong

Grab your cape.
Standardization is essential as more cell therapies near commercialization

Adding to the burden, center directors say, is that each company with a product or experimental therapy insists on performing its own audit to ensure its collection protocols are followed.

“We’re auditing the same process again and again,” said Heather Steinmetz, the quality assurance manager for UCLA’s program.
Opportunities exist for standardization throughout the cell therapy supply chain

FY19 standardization initiatives

Grab your cape.
Supporting our **Collection Center Network and clients**

- **Be The Match BioTherapies promotes consistency and quality by:**
  - Understanding client collection and processing requirements, and developing a network of centers to meet those needs
  - Providing training for centers based on client specifications and requirements
  - Ensuring sites meet critical accountabilities, milestones and deliverables
  - Delivering prompt, ongoing customer service and technical support to Network centers
  - Helping centers identify inefficiencies in operations and implement solutions
  - Monitoring and reporting site performance and quality indicators
Adding industry efficiencies through Quality System Audit Program

• **Cell and gene therapy companies can license quality system audit results**
  – Evaluates apheresis center and cell therapy lab compliance with FDA Good Tissue Practice and Good Manufacturing Practice regulations
  – All auditors certified by the American Society for Quality
  – Audits and re-audits performed on a two-year rolling cycle
  – Ensures quality compliance across broad collection center networks, while saving costs and minimizing audit burden

• **Audit results include:**
  – Audit report
  – Audit checklist
  – Audit findings response
  – Audit closure letter

Grab your cape.
Thank you!