



ACTIVITY: EVALUATING COMPLIANCE

9:30 AM

Michele Sugrue, MS, MT(ASCP)SBB

The presenter will help facilitate case studies. The audience will identify what challenges the program faces after each case. The presenter will poll the audience to determine what standards may not be in compliance. Ultimately, the presenter, with the help of the audience, will answer how the program can achieve compliance with FACT Standards and continue FACT accreditation.

ACCREDITATION SUCCESS STORY

10:00 AM

Quality Management Matters: Working as a Team to Create a Cohesive Quality Management Program: Intermountain Blood and Marrow Transplant Program and American Red Cross, Lewis and Clark Region.

BREAK

10:15 AM

CREATING A COHESIVE QUALITY MANAGEMENT PROGRAM WITH AN OUTSIDE COLLECTION CENTER

10:30 AM

Nicole AQUI, MD

Nicole AQUI, MD, will review the standards in section B and C that explicitly mention contact and/or connection between the Clinical and Collection Facilities, and the importance of how to incorporate these into your quality management plan.

CORRECTION OF DEFICIENCIES

11:15 AM

Joseph Schwartz, MD, MPH

Joseph Schwartz, MD, MPH, will explain the most common challenges in apheresis and construct a plan to correct the deficiencies.

ACTIVITY: DISSECTING DEFICIENCIES

11:45 AM

Joseph Schwartz, MD, MPH

Joseph Schwartz, MD, MPH, will practice evaluating deficiencies with the audience and recommend correction

SPEAKERS



Joseph Schwartz, MD, MPH
Mount Sinai Bone Marrow and Transplantation Program



Huy Pham, MD, MPH
Be the Match Collection Services



Scott Koepsell, MD, PhD
University of Nebraska Medical Center



Michele Sugrue,
UF Health Shands Hospital



Nicole AQUI, MD
University of Pennsylvania Medical Center

REGISTRATION

7:30 AM

OVERVIEW OF THE FACT ACCREDITATION PROCESS

8:00 AM

Phyllis I. Warkentin, MD

Phyllis I. Warkentin, MD, will describe the accreditation process from application to accreditation. She will define common terminology for the accreditation process and explain the function of the accreditation coordinator. Dr. Warkentin will also summarize the inspector's role in the process of accreditation. The audience will participate in interactive knowledge checks throughout the presentation.

THE KEY TO COMPLIANCE SUCCESS

9:00 AM

Michele Sugrue, MS, MT(ASCP)SBB

The presenter will review the entire compliance application process and identify documents required for submission.

LUNCH

12:15 PM

WHAT TO EXPECT DURING THE INSPECTION

12:45 PM

Michele Sugrue, MS, MT(ASCP)SBB

Michele Sugrue, MS, MT(ASCP) SBB, will review apheresis program requirements during a FACT inspection and list tips and identify strategies to help apheresis programs navigate a successful inspection process.

ACTIVITY: PRACTICE A GUIDED TOUR

1:15 PM

Scott Koepsell, MD, PhD

Scott Koepsell, MD, PhD, will show an apheresis tour video. The audience will be provided with a tour checklist and will mark compliant or not compliant next to the Standards applicable to the tour.

ACCREDITATION SUCCESS STORY

2:00 PM

**Managing Immune Effector Cell
Collections for Multiple Manufacturers**

BREAK

2:15 PM

LABELING AND CHAIN OF IDENTITY AND CUSTODY FOR IEC PRODUCTS COLLECTED IN APHERESIS FACILITIES

2:30 PM

Scott Koepsell, MD, PhD

Scott Koepsell, MD, PhD, will review IEC Standards related to product identification and chain of identity and custody. He will also explain FACT expectations for clinical trial and commercial product identification and chain of custody from bench to bedside, describe how ISBT 128 coding and labeling can be used with clinical trial and commercial cellular therapy products and determine if a label unambiguously identifies the correct product.

GROWING VARIATIONS IN COLLECTION REQUIREMENTS

3:15 PM

Huy Pham, MD

Huy Pham, MD, will evaluate the differences in collection requirements for two different cellular therapy products.

ACCREDITATION SUCCESS STORY

4:00 PM

**Using OneNote to maintain FACT
readiness: Baylor College of
Medicine**

MAINTAINING FACT READINESS

4:15 PM

Joseph Schwartz, MD, MPH

Joseph Schwartz, MD, MPH, will discuss developing a plan for continuous accreditation readiness. He will also explain how regular self-assessment of your program will help maintain readiness, and how to prepare employees so that accreditation is maintained.

CLOSING

5:00 PM

